S. HRG. 104–309

MEDICARE PAYMENTS FOR MEDICAL SUPPLIES

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED FOURTH CONGRESS

FIRST SESSION

Oct 2, 1995

SPECIAL HEARING

Printed for the use of the Committee on Appropriations

U.S. GOVERNMENT PRINTING OFFICE

21–950 cc WASHINGTON : 1996

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-052254-4

COMMITTEE ON APPROPRIATIONS

MARK O. HATFIELD, Oregon, *Chairman*

TED STEVENS, Alaska
THAD COCHRAN, Mississippi
ARLEN SPECTER, Pennsylvania
PETE V. DOMENICI, New Mexico
PHIL GRAMM, Texas
CHRISTOPHER S. BOND, Missouri
SLADE GORTON, Washington
MITCH McCONNELL, Kentucky
CONNIE MACK, Florida
CONRAD BURNS, Montana
RICHARD C. SHELBY, Alabama
JAMES M. JEFFORDS, Vermont
JUDD GREGG, New Hampshire
ROBERT F. BENNETT, Utah

ROBERT C. BYRD, West Virginia
DANIEL K. INOUYE, Hawaii
ERNEST F. HOLLINGS, South Carolina
J. BENNETT JOHNSTON, Louisiana
PATRICK J. LEAHY, Vermont
DALE BUMPERS, Arkansas
FRANK R. LAUTENBERG, New Jersey
TOM HARKIN, Iowa
BARBARA A. MIKULSKI, Maryland
HARRY REID, Nevada
J. ROBERT KERREY, Nebraska
HERB KOHL, Wisconsin
PATTY MURRAY, Washington

J. KEITH KENNEDY, *Staff Director*
MARK VAN DE WATER, *Deputy Staff Director*
JAMES H. ENGLISH, *Minority Staff Director*

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

ARLEN SPECTER, Pennsylvania, *Chairman*

MARK O. HATFIELD, Oregon
THAD COCHRAN, Mississippi
SLADE GORTON, Washington
CONNIE MACK, Florida
CHRISTOPHER S. BOND, Missouri
JAMES M. JEFFORDS, Vermont
JUDD GREGG, New Hampshire

TOM HARKIN, Iowa
ROBERT C. BYRD, West Virginia
ERNEST F. HOLLINGS, South Carolina
DANIEL K. INOUYE, Hawaii
DALE BUMPERS, Arkansas
HARRY REID, Nevada
HERB KOHL, Wisconsin

Majority Professional Staff
CRAIG A. HIGGINS and BETTILOU TAYLOR

Minority Professional Staff
MARSHA SIMON

Administrative Support
MEG SNYDER

CONTENTS

MEDICARE PAYMENTS FOR MEDICAL SUPPLIES

MONDAY, OCTOBER 2, 1995

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:34 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Tom Harkin presiding.

Present: Senator Harkin.

GENERAL ACCOUNTING OFFICE

STATEMENT OF JONATHAN RATNER, ASSOCIATE DIRECTOR, HEALTH CARE FINANCING ISSUES, HEHS

ACCOMPANIED BY DON WALTHALL, SENIOR ANALYST

OPENING REMARKS OF SENATOR TOM HARKIN

Senator HARKIN. Good morning. The Subcommittee on Labor, Health and Human Services of the Appropriations Committee will come to order.

This is another in this subcommittee's series of hearings going back over 5 years to examine the extent to which taxpayers and the elderly are ripped off by fraud, waste, and abuse in the Medicare Program. Today's hearing will focus on waste and abuse in Medicare's payment for medical supplies.

This hearing comes at a critical time. Congress is on the brink of cutting Medicare. By how much, we do not know yet. By one estimate, as much as $270 billion, which would include a doubling of premiums and deductibles paid by the elderly and disabled.

But I have been saying for some time that the first thing we should do is cut the waste. This subcommittee has documented case after case of Medicare losing billions of dollars through excessive payments, double billing, outright fraud, antiquated computer systems and payments for outrageous items like trips to Italy by health care executives to inspect artwork.

Today we will focus on money lost in payments for medical supplies. Last year alone, Medicare was billed for $6.8 billion for these items.

We will hear from the GAO and the HHS inspector general, both of whom have done considerable work in this area. Their findings are disturbing.

The GAO found that Medicare often has no idea what medical supplies it is paying for. Claims submitted by providers are often not itemized, and thus Medicare has no way of determining the reasonableness of the claims.

To find out whether this approach was leading to waste and abuse, the GAO selected a sample of claims for medical supplies that Medicare had already paid.

The result: 89 percent of the claims should have been partially or totally denied, and 61 percent of the dollars paid out should not have been paid at all.

The GAO and the inspector general took a specific look at Medicare payments for surgical dressings, sometimes called wound care supplies. That is bandages, gauze, tape, other items used on open cuts and bed sores.

Last year, HCFA added at least 29 types of bandages and related supplies to the list of covered services and expanded the circumstances under which they would be paid.

Despite HCFA's assurances to this subcommittee to the contrary, the GAO and the inspector general found that HCFA began paying claims under the expanded benefit without having any reasonable controls against abusive and excessive billings.

As a result, GAO found that utilization rates for these newly covered items, the number of items billed for Medicare patients, was on average nearly three times higher than for previously covered supplies.

GAO found specific examples of abuse caused by this irresponsible action by HCFA that would be humorous if it were not so costly to the taxpayers. What do I mean by humorous? Well, GAO found that some nursing homes were being paid for up to 240 yards per day, per individual, for tape.

The inspector general found a case in which Medicare had paid for 12.5 miles of tape for a patient over a 6-month period of time. As I said, if it were not so costly, it would be humorous.

The inspector general found that 66 percent of Medicare part B payments for wound care supplies were likely unnecessary, that 80 percent of payments for transparent film were found to be questionable.

In addition to the lack of inadequate payment controls, the inspector general found that in 23 percent of the nursing home surveyed wound care supplier representatives—that is, those selling the products and not the patient's doctor or nurse—were deciding the amount of supplies delivered to a patient each month, almost one out of four.

Not the patient's doctor or nurse deciding how many bandages someone gets, but the supplier themselves. What a sweetheart deal that is.

Also, 17 percent of nursing homes paid by Medicare for wound care supplies surveyed by the inspector general had been offered inducements in exchange for allowing suppliers to provide wound care products to patients. Inducements included diamond rings, blenders, and cameras.

The GAO also found that Medicare payment rates for surgical dressings were excessive to the point that if we just paid the lowest

retail rate—we would reduce payments for surgical dressing by roughly one-half.

Here is one right over here. I will just have Peter hold that up. This is something I just did on my own. I just had my staff in Iowa go out, different cities in Iowa, to find—we had a certain bandage.

I had them here. I do not see them now. Go out and price them. And it ranged from about 11 cents to about 24 cents. The average was 17 cents.

Medicare pays 86 cents for the same or similar bandages. That is just what we found in drugstores in Iowa; 405 percent more that Medicare is paying than we found in a retail drugstore in the State of Iowa, and Medicare pays 405 percent more than that.

You are going to hear me talk today about Medicare and competitive bidding and trying to get the best wholesale price. Maybe we ought to just send them out to the local drugstore, do a little shopping, down to Wal-Mart or someplace like that. They would probably get a lot better than what they are doing right now.

So the need for reform is clear, and I look forward to hearing from GAO and the inspector general and HCFA about what is going on and why it is going on and what can be done to get to the bottom of it.

I want to get the witnesses' assessment of the impact of the proposed Medicare changes on the fight against Medicare fraud, waste, and abuse. I asked the inspector general to review provisions of the House Ways and Means plan. I was disturbed again by their findings.

This morning I am releasing the inspector general's response to me in which the inspector general says, and I quote:

> If enacted, certain major provisions of H.R. 2389 would cripple the efforts of law enforcement agencies to control health care fraud and abuse in the Medicare program and to bring wrongdoers to justice.

The bottom line of this analysis is that while purporting to cut abuse, in fact this plan would frustrate law enforcement's efforts to stop kickback schemes and other fraudulent activities. So it goes in exactly the wrong direction.

So I hope this hearing will point us in the right direction that we should go and point out what we can do to save our taxpayers a lot of money. And we are not just talking about a little bit of money. We are talking about a lot of money.

If I am not mistaken, this year Medicare is going to spend about $180 billion a year. Now, if the GAO is right that up to 10 percent of that goes for fraud, waste, and abuse, you can figure it yourself.

That is up to $18 billion a year times 7 years. That is $126 billion over 7 years, potential savings by cutting out fraud, waste, and abuse.

Now, I am not so naive as to think we will get every penny of it, but what if we just got half of it? What if we got $60 billion over the next 7 years?

With that, I would like to ask the first panel, Jonathan Ratner, Associate Director of Health Financing Issues, U.S. General Accounting Office, and also George Grob, Deputy Inspector General for Evaluation and Inspections, Office of Inspector General, Department of Health and Human Services, to come up to the table.

[Pause.]

Senator HARKIN. Mr. Grob and Mr. Ratner, welcome again to this committee.

If you would identify who you have with you, Mr. Ratner.

Mr. RATNER. I have Don Walthall, who is a senior analyst at GAO.

Senator HARKIN. Very good. Appreciate your being here.

The second panel will be Mr. Vladeck, the Administrator of HCFA, and the third panel will be Robert Clock, CEO of Clock Medical Supply Co., of Winfield, KS.

This hearing will wrap up around about 11:15 a.m. So we have 1½ hours.

SUMMARY STATEMENT OF JONATHAN RATNER

With that, Mr. Ratner, again, I welcome you to the committee. I read your report, as you can imagine. And I just turn it over to you for any statements and comments that you have.

And I just say for all of the witnesses, any written statements you have will be made a part of the record in their entirety.

Mr. Ratner, please proceed.

Mr. RATNER. Thank you, Mr. Chairman.

We are pleased to be here today to contribute to the debate over the fundamentals of the Medicare Program and its management.

As I mentioned, with me today is Don Walthall, a senior analyst, who worked in this area and on this report.

GAO recently issued another report that recommends ways to garner savings from Medicare by adopting the modern management strategies of successful private insurers and employers. In that report, we make two points that today's subject dramatically illustrates.

One, that for many services and supplies, the Medicare payment far exceeds what you might pay in the marketplace. And second, that Medicare's scrutiny of incoming claims is too often inadequate to reveal overpricing or oversupply.

Today we are here to discuss a report prepared, as you have mentioned, at your request, to examine Medicare's payments for medical supplies, including surgical dressings. This report makes several points.

First, for surgical dressings, Medicare often pays too much, as you have discussed, more than wholesale and many retail prices.

Why? Because October 1993 legislation requires HCFA to use a fee schedule for surgical dressings that locks prices in. As a result, Medicare reimbursement is on auto pilot. HCFA lacks the flexibility to adjust these prices down even when market prices drop.

As you can see from our chart, if HCFA had paid wholesale prices for 44 types of surgical dressings, the total savings would be almost $20 million each year. That is, reimbursing at wholesale would save Medicare over one-third of what it pays now.

Senator HARKIN. You are talking about this chart over here, right, Mr. Ratner?

Mr. RATNER. The blue chart here, yes, sir.

Senator HARKIN. OK. So you had number of dressings compared, 44 on the wholesale line. The fee schedule—what HCFA paid was $57 million.

Mr. RATNER. Indeed.

Senator HARKIN. The compared wholesale price was $37 million. Is that right?

Mr. RATNER. That is right.

Senator HARKIN. That is the wholesale price. OK. Continue on. I just wanted to make sure I am reading that correctly.

And then you say the lowest retail price of the same was—I do not understand how come it is—now that $57 million is $48 million.

Mr. RATNER. I would be happy to elaborate there.

Senator HARKIN. All right. Go ahead.

Mr. RATNER. Really, what we are talking about here are different comparisons of the prices that Medicare has to pay under the fee schedule to alternative benchmarks.

We sought to compare the different types of surgical dressings that Medicare pays for to these alternative benchmark prices. And with different benchmarks, you have different matches.

So in the case we just were discussing, the wholesale case, we were able to match 44 of the 63 types of surgical dressings, and we estimated that Medicare would have spent then about $57 million under the fee schedule.

Under the alternative wholesale price, it would have spent $37 million, a savings of $20 million, about one-third of what it pays now.

If you take another example, let us say, of what the Department of Veteran Affairs paid for dressings, we were able to match theirs for just nine dressings. Nonetheless, the savings again would have been substantial, over $9 million. Indeed, we went out to four Los Angeles area drugstores, picked the lowest retail prices there. And again, by chance, we were able to match nine surgical dressings. The potential savings would have been more than $2 million.

The second point is that part A claims processors—these are the contractors who deal with hospitals and other institutional providers—do not know the specific items they are paying for when they receive a claim.

You could have a $21,000 claim. It could be for a pacemaker or it could be for a truckload of 79 cent surgical sponges. That is because the institutional providers are allowed to bill all medical supplies under 10 broad codes, and the items are not listed individually.

So, for example, we found pacemakers and surgical dressings both under this broad code 270. This reliance on broad codes makes it hard for Medicare to question whether charges are reasonable.

Let me illustrate. When we tested a sample of high dollar claims and traced what specific items were being billed, we asked the institutional providers to resubmit their claims with an itemized list.

These are claims that the Medicare contractor had paid automatically, that is, without review, the first time around.

After our test, the contractor reviewed the claims and then denied, as we mentioned, in whole or in part nearly 90 percent of those for which providers sent in the requested documentation. Some providers did not produce the documentation requested. And in this case, then, the contractor denied all their claims.

We had here just a total of 85 claims in our sample taken from claims submitted over a 1-month period. And yet, that total num-

ber of claims yielded denials that amounted to over one-half million dollars.

The third point is that part B claims processors who deal with physicians and with medical supply companies also have difficulty questioning whether charges are excessive, but they have a different reason.

They process and pay claims automatically unless computerized controls in their system stop payment under certain conditions, such as exceeding a utilization threshold.

The contractors have many such controls, including for some surgical dressings. But the contractors do not have controls for certain medical supplies like—at least until yesterday—29 categories of surgical dressings that constitute a newly covered Medicare benefit.

Unless the contractor formally establishes criteria that specify the conditions under which payment will be made—and this is what HCFA calls medical policies—the contractor has no basis for questioning or for identifying questionable claims.

Without a formal medical policy in effect, it seems as though anything goes. As a result, contractors are paid many high dollar, high volume surgical dressing claims with nothing to trigger an examination of these claims before payment.

In fact, our review found that the number of dressings billed per beneficiary was on average nearly three times higher than the newly covered dressings. That is three times higher compared to the dressings for which medical policies had already been established.

Now, according to HHS, the medical policies covering these new surgical dressing benefits went into effect yesterday, October 1. We applaud that. But the lesson remains. Medical policies should be established before the coverage of new benefits goes into effect.

One last point on these medical policies. They are a striking example of what happens when you do not have a medical policy in place, and this concerns claims Medicare paid for adhesive tape.

During a 15-month period, suppliers billed for an average of 60 rolls of tape per beneficiary. But during that same period, Medicare paid one supplier for an average of 268 rolls of tape for each beneficiary, a large excess, yet there was no trigger for examination.

One final point that we are making here: Neither part A nor part B claims processing contractors can readily cross reference the payment records to determine whether duplicate payments are being made. The reason is that the part A contractors do not receive itemized bills.

Since the bills part A and part B contractors receive are not in the same format, a cross-walk between them is not possible without getting more documentation from the part A billers.

So here is what can happen: Last year, a part A contractor paid a nursing home for two bedside drainage bags used by a patient during a 1-month stay. Meanwhile, for the same patient, a part B contractor had paid the supplier for 30 drainage bags.

Contractors had no computerized controls to prevent such duplicate billings.

Senator HARKIN. Please, Mr. Ratner, say that again for me. Under part A——

Mr. RATNER. Under part A, you had the contractor being billed for two of these drainage bags in the month for a given patient.

Senator HARKIN. Under part A. That is under hospital.

Mr. RATNER. That is right. Under the hospital. But then, from the medical supply side, part B, the same patient was supposed to receive 30 drainage bags, and Medicare paid for those.

Senator HARKIN. The same supplier?

Mr. WALTHALL. In the part A case, the billing was by the nursing home. In the part B case, it was the supplier that did the billing.

Senator HARKIN. But what I am asking is, is it the same supplier that supplied the nursing home?

Mr. WALTHALL. We do not know whether that is the case or not.

Senator HARKIN. But we do know it is the same patient.

Mr. WALTHALL. The same patient.

Senator HARKIN. The same individual was billed for two by the nursing home and billed for how many by the supplier?

Mr. RATNER. Thirty.

Senator HARKIN. Thirty by the supplier. Well, it must have been the same supplier, if they are supplying the nursing home.

Mr. WALTHALL. It could be the same supplier, but it does not necessarily have to be.

Senator HARKIN. Did you look into whether or not this patient actually used 30 of these bags? Is it possible to use 30? I do not know anything about this issue. I mean——

Mr. WALTHALL. I think it would be difficult to use 30 drainage bags in that time period.

Senator HARKIN. What time period?

Mr. WALTHALL. One month.

Senator HARKIN. One month. So the supplier put in for 30, and that was paid by HCFA.

Mr. WALTHALL. Yes.

Senator HARKIN. Would this be fraudulent? Do we know if HCFA took any action against this supplier?

Mr. WALTHALL. This is something that, at the minimum, we would suggest needs review.

Senator HARKIN. But you have no knowledge as to whether or not in this particular case HCFA went after the supplier for fraud.

Mr. WALTHALL. No.

Senator HARKIN. You are just telling me—you are basically just saying that you have one patient in a nursing home. There is going to be put in for two incontinence bags for 30 days. The supplier put in for 30 for the same person.

Mr. WALTHALL. Right.

Senator HARKIN. And because of a lack of, what, computers or cost checks, they were not able to catch this or what?

Mr. RATNER. The basic point is on one side, there is itemizing going on. And so you can see what it is that you are paying for.

Senator HARKIN. That is the part B. That is the part B side.

Mr. RATNER. That is the part B side. On the part A side, there is no itemizing. And so you cannot then compare to see whether you have paid for the same thing because you do not know what you have paid for on this side.

Senator HARKIN. But it was part B, though, where they listed the 30 of them.

Mr. RATNER. That is true. Well, the point that we are making here really is that there is this payment for the same patient, and that is the point that we are emphasizing.

I think the thing that you are picking up on is that, in addition, there is a question whether 30 is within the bounds of reasonableness, and is that something that itself should call for review.

Senator HARKIN. So there are two issues. There is the cross-checking between A and B and plus, also, just the checking on B itself.

Mr. RATNER. Yes.

Senator HARKIN. OK.

Mr. RATNER. Over the past several years, Medicare has taken steps to reduce unnecessary payments for surgical dressing and medical supplies, and the most important is the establishment of regional centers for durable medical equipment and related supplies.

This is quite important, but several actions still are needed to fix Medicare's payment rate problems and its payment control inadequacies.

First, HCFA needs greater authority to adjust these fee schedule prices quickly when market conditions warrant such changes.

To allow Medicare to take advantage of the lower prices out in the marketplace, we believe that Congress should consider granting HCFA or its contractors the authority to modify prices promptly for durable medical equipment and medical supplies.

Second, HCFA should require providers that bill part A contractors to itemize the claims for medical supplies. This is required on the part B side. If it was required for part B, it would help contractors not only identify unreasonable charges but cross-reference the payment of claims by part B contractors.

Third, when new benefits are introduced, HCFA should direct its contractors to implement controls based on medical policies that would flag high dollar, high volume claims before they are paid.

PREPARED STATEMENT

In sum, Medicare has made some progress in this area, but the actions that we point to here we think would curb unnecessary payments further.

Mr. Chairman, that concludes my statement.

Senator HARKIN. Thank you very much, Mr. Ratner.

[The statement follows:]

STATEMENT OF JONATHAN RATNER

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to contribute to the debate over the fundamentals of the Medicare program and its management. We recently issued a report, based on an extensive body of GAO work over the last few years, that recommends the need for modern management strategies to help curb waste, fraud, and abuse in the Medicare program.[1] In that report, we note that for many supplies and services, the Medicare payment far exceeds market rates. We also report that the scrutiny of incoming claims is often inadequate to reveal overpricing or oversupply.

Today, I would like to discuss a report we prepared at your request to examine Medicare's payments for medical supplies, including surgical dressings.[2] Our findings provide a striking illustration of Medicare's excessive payment rates and the inadequacy of its payment controls.

In brief, this report makes several points:

-- When compared with wholesale and many retail prices, Medicare's payment rates for surgical dressings are generally excessive.

-- Medicare contractors that process claims for hospitals, nursing homes, and other institutions are unable to identify the specific items Medicare is being billed for, which makes it difficult for the contractors to determine whether the total charges are reasonable.

-- Medicare contractors that process claims for physicians and other providers have paid for some types of surgical dressings without reviewing high-dollar claims before payment.

-- Medicare's two types of claims processing contractors cannot cross-reference payment records to determine whether duplicate payments are being made.

Despite recent improvements in the way Medicare monitors payments for medical supplies, problems with high payment rates and controls over payments for supplies persist. Several actions, as addressed in our report, are needed to fix these problems. First, the Congress could grant the Health Care Financing Administration (HCFA) the legislative authority to set payments at rates more favorable to large volume purchasers. Second, HCFA could require institutional providers to itemize their claims for medical supplies. This would help contractors not only identify unreasonable charges but also cross-reference the payment of claims by another contractor. Third, HCFA could direct its contractors, when new benefits are introduced, to implement controls that would flag for review high-dollar and high-volume claims before they are paid.

BACKGROUND

Medicare provides health insurance coverage for approximately 37 million elderly and disabled people under two

---

[1] Medicare Spending: Modern Management Strategies Needed to Curb Billions in Unnecessary Payments (GAO/HEHS-95-210, Sept. 19, 1995).

[2] Medicare: Excessive Payments for Medical Supplies Continue Despite Improvements (GAO/HEHS-95-171, Aug. 8, 1995).

parts: part A, primarily hospital insurance, and part B, supplementary insurance. HCFA, an agency within the Department of Health and Human Services (HHS), is responsible for Medicare administration and oversight. HCFA contracts with insurance companies, called fiscal intermediaries for part A and carriers for part B, to process, review, and pay claims for covered services.

Payments for medical supplies are made under either of Medicare's two parts. Medical supply claims submitted by hospitals or other institutions, such as nursing homes or home health agencies, are paid by 43 fiscal intermediaries located throughout the country. Before October 1993, medical supply claims submitted by noninstitutional providers, such as physicians or medical supply companies, were paid by 32 carriers. In October 1993, in response to legislation, HCFA started consolidating carrier claims processing responsibility for durable medical equipment (DME), prosthetics, orthotics, and medical supplies, including surgical dressings, at four regional carriers, which are commonly referred to as DMERCs, Durable Medical Equipment Regional Carriers.

In March 1994, HCFA greatly expanded its surgical dressing benefit, broadening the types of dressings covered and the conditions under which they would be covered. For example, the benefit was expanded to cover payment for various types and sizes of gauze pads that Medicare previously did not cover. Also, the duration of coverage was extended from 2 weeks to whatever is considered medically necessary.

MEDICARE SURGICAL DRESSING PAYMENTS ARE GENERALLY EXCESSIVE

For surgical dressings, Medicare often pays too much--more than wholesale and many retail prices. When we compared the rates that Medicare pays for surgical dressings with other available prices, we found that Medicare's fee-schedule payments are generally excessive compared with wholesale prices, prices paid by the Department of Veterans Affairs (VA), and even retail prices. Overall, we estimate that HCFA could save substantial amounts if its fee schedule were calculated on the basis of lower available prices. For example, as shown in table 1, if HCFA paid wholesale prices for 44 surgical dressings, total savings would be almost $20 million, or almost 35 percent of what it now pays. Potential savings for just nine dressings would be more than $9 million if HCFA paid the lowest rate that the VA paid for the dressings. Even if HCFA had paid the lowest retail rates found at four Los Angeles area drug stores for nine surgical dressings, potential savings would be more than $2 million.

Table 1: Potential Medicare Savings on Surgical Dressings

		Estimated 1995 expenditures		Potential savings	
Type of price compared	Number of dressings compared	Fee schedule	Compared price	Dollars	Percent of fee schedule
Wholesale	44	$57,113,852	$37,388,654	$19,725,197	34.54
Lowest retail	44	48,089,936	25,762,198	22,327,741	46.42
Actual retail	9	17,984,235	15,967,898	2,016,337	11.21
VA	9	17,055,044	7,871,643	9,183,401	53.85

The method HCFA used to calculate the fee schedule for surgical dressings caused these high payments. The Omnibus Budget Reconciliation Act of 1993 (OBRA 1993) required HCFA to establish a fee schedule for surgical dressings by computing the average historical charges for the dressings. Because it had decided to expand the coverage for the types of surgical dressings it would pay for, however, HCFA did not have data on historical charges. Instead, HCFA used retail surgical dressing supply catalogs to create a price list for each type of covered surgical dressing. The amount of the median-priced dressing for each type became the fee-schedule amount.

If HCFA makes a mistake in calculating the fee schedule, it can correct the mistake (for example, if it used wholesale prices instead of retail prices). However, HCFA cannot change the methodology for determining the fee schedule nor can it adjust the fee schedule downward, even if the prices of dressings drop.

For certain DME items--but not for surgical dressings and other medical supplies--the Secretary of HHS can adjust prices that are not inherently reasonable.[3] In these cases, the authority is very limited and involves a complex set of procedures that can take a lengthy amount of time--as long as 3 years--to complete.

We believe that the fee-schedule approach to setting prices provides a good starting point for setting appropriate Medicare prices. As we have reported several times, however, HCFA needs greater authority and flexibility to quickly adjust fee schedule prices when market conditions warrant such changes. To allow Medicare to take advantage of competitive prices, the Congress should consider authorizing HCFA or its carriers to promptly modify prices for DME and other medical supplies.

FISCAL INTERMEDIARIES DO NOT KNOW WHAT SUPPLIES THEY PAY FOR

Fiscal intermediaries do not know what they are paying for when processing claims for medical supplies. For part A claims, surgical dressings are not separately identifiable or billable. Rather, they are included in a broad medical supply category. The claims submitted by providers have no detailed information that would allow fiscal intermediaries to assess their reasonableness. This lack of detail exists because HCFA guidance allows providers to bill all medical supplies under 10 broad codes; billed items are not listed by type or amount. A code frequently used to record medical supplies, code 270, includes many different items. As a result, a $21,000 claim could be for a pacemaker or a truckload of 79-cent surgical sponges. This makes it difficult for the contractor to question whether charges are reasonable.

To gauge the potential impact of requiring itemization instead of billing under such broad codes, we requested that a fiscal intermediary obtain the medical records and an itemized list of supplies supporting 85 high-dollar medical supply claims submitted during a 1-month period. All of these claims had been processed without any review. The fiscal intermediary's subsequent review found that 89 percent of the claims for which documentation was received should have been totally or partially denied; and almost 61 percent of the dollars billed for these claims should have been denied for various reasons, including items not medically necessary, not covered by Medicare or covered as part of routine or administrative costs, no documentation of supplies used, no doctors' orders, and no itemized list of supplies. All claims for which documentation was not received were subsequently denied.

[3] 42 U.S.C. 1395m(a)(10)(B).

Legislation Partially Addresses Problem

OBRA 1993 partially addressed the broad billing code problem.[4] The legislation provided essentially for certain supplies, including surgical dressings, to be paid based on the fee schedule DME carriers use in the part B program. As a result, providers must submit such claims to fiscal intermediaries with an itemization of the specific supplies and quantities being billed. Because the provision does not apply to all medical supplies, however, many other types of medical supplies will still be billed using broad codes that do not adequately describe the types and amounts of such supplies being billed. Also, the OBRA 1993 provision does not apply to surgical dressing claims submitted by home health agencies, which billed Medicare for almost half a billion dollars of medical supplies in 1994.

As we recommend in our report, the Secretary of HHS should direct the HCFA Administrator to require that all part A bills itemize medical supplies. Related legislation for surgical dressings should be expanded to include all medical supplies and should apply to all providers billing the program, including home health agencies. Such itemization is required of all part B providers.

DME CARRIERS HAVE PAID HIGH-DOLLAR CLAIMS WITHOUT QUESTION

Carriers have paid without question many high-dollar, high-volume part B surgical dressing claims. As of the end of fiscal year 1995, the DME carriers had not established important fraud and abuse controls that would trigger a review of claims. Specifically, the 29 surgical dressings covered as a result of the expanded surgical dressing benefit did not have formal criteria--called medical policies--specifying the conditions under which payment will be made. Without these policies, DME carriers have had no basis for identifying questionable claims.

We found that the utilization level--the number of dressings billed per beneficiary--was, on average, nearly three times higher for the newly covered dressings, that is, those without formal medical policies. Moreover, on average, the dressings not covered by medical policies exceeded the expected utilization level, as determined by recommended industry and draft DME carrier standards. In some cases, the average number of dressings billed per beneficiary was four times greater than expected.

A striking example of payments made in the absence of medical policies concerns claims Medicare paid for adhesive tape. During a 15-month period, suppliers billed for an average of 60 rolls of tape per beneficiary. Medicare paid one supplier, however, for an average of 268 rolls of tape per beneficiary during that period.

HCFA expanded surgical dressing coverage and instructed DME carriers to pay for newly covered surgical dressings before the carriers had a chance to develop new medical policies. As a result, most claims for surgical dressings that did not have payment policies were paid without a routine review to determine whether the amount of dressings billed was reasonable or medically necessary.

---

[4]P.L. 103-66, section 13544, 107 Stat. 312, 589.

As of yesterday, the DME carriers put into place the medical policies covering new surgical dressing benefits, according to HHS. But the losses Medicare incurred until these policies were in place serve as a lesson for all newly covered benefits. As our report recommends, HCFA should, as a matter of course, develop and get approval for medical policies before the coverage of new benefits goes into effect.

MEDICARE SYSTEM IS VULNERABLE TO DUPLICATE PAYMENTS

Medicare does not have effective tests to determine whether both DME carriers and fiscal intermediaries are paying for the same surgical dressings, medical supplies, and other items. As a result, nothing prevents Medicare from paying for the same item twice.

Surgical dressings and many medical supplies can be billed to either fiscal intermediaries or DME carriers, but Medicare does not have an effective control to prevent both types of contractors from paying for the same medical supplies or surgical dressings. Our review found evidence that Medicare has made such duplicate payments. In one instance, a fiscal intermediary paid a nursing home for 2 bedside drainage bags used by a patient during a 1-month stay, while, for the same patient, a DME carrier also paid a supplier for 30 drainage bags.

As we recommend in our report, HCFA needs to establish procedures to prevent duplicate payments by fiscal intermediaries and carriers. HCFA should be able to establish such procedures without too much difficulty if providers billing part A intermediaries were required to itemize medical supplies as we have recommended. Fiscal intermediaries and DME carriers both would receive claims that are itemized and, therefore, are in a similar format, making it easier for contractors to identify duplicate payments.

IMPROVEMENTS MADE IN MONITORING MEDICAL SUPPLY PAYMENTS

Recent monitoring improvements should help reduce Medicare's vulnerability to fraud and abuse in this area. The consolidation of DME and medical supply claims processing at four regional carriers has several advantages. Medical supply and surgical dressing claims can receive more attention now than previously from local carriers. DME carriers specialize in processing these types of claims and are in a better position to detect and prevent payment of abnormally high claims for medical supplies. The consolidation also makes it easier to compile comprehensive national data--that were not available previously--on medical supply utilization and payments.

In 1993, HCFA also developed a programwide emphasis on data analysis. Calling its approach focused medical review, HCFA required contractors to begin identifying general spending patterns and trends that would allow them to identify potential problems. Fiscal intermediaries have started implementing this approach and some have identified the different types and number of claims that Medicare may be paying inappropriately. For example, as a result of one focused review, an intermediary denied 85 percent of the claims reviewed during a 1-month period, saving $5.8 million.

Moreover, some intermediaries have estimated how much Medicare can potentially save by tightening prepayment review controls. One intermediary identified eight problem areas, in addition to those it was already reviewing, that should be reviewed because of such things as precipitous increases in

utilization rates. The intermediary estimated that focused reviews of these areas could save $57 million, but it did not have the resources to conduct these reviews.

Armed with this new information from DME carriers and focused medical review reports, HCFA is now much better positioned than in past years to provide HHS, the Office of Management and Budget, and the Congress with concrete information on contractor activities that save program dollars.

CONCLUSIONS

Despite HCFA's claims monitoring improvements, some problems in paying for medical supplies remain for several reasons. The inflexibility of Medicare's fee schedule results in payment rates that are higher than wholesale and many retail prices. In addition, in the case of many part A claims, claims processing contractors do not know what they are paying for, and in the case of part B claims, have not had a basis for questioning unreasonably high charges. Neither type of contractor has been able to test claims for possible duplicate payments. For this combination of reasons, Medicare has lost hundreds of millions of dollars in unnecessary payments.

We make several recommendations in our report to help correct these problems. By obtaining the legislative authority to modify payment rates in accordance with market conditions, requiring providers to itemize claims, and introducing the relevant medical policies before paying for new benefits, HCFA could reduce its dollar losses related to medical supply payments. Contractors could avoid paying unreasonable charges and making duplicate payments.

Mr. Chairman, this concludes my prepared statement. At this time, I will be happy to answer any questions you or other Members of the Subcommittee may have.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE INSPECTOR GENERAL

STATEMENT OF GEORGE GROB, DEPUTY INSPECTOR GENERAL FOR EVALUATION AND INSPECTIONS

Senator HARKIN. Mr. Grob, welcome to the subcommittee, and you are here representing Ms. Brown.

Mr. GROB. The Inspector General's Office, yes.

Senator HARKIN. Thank you very much. Please proceed.

Mr. GROB. Thank you very much.

Senator, today the Inspector General June Gibbs Brown will be releasing the final versions of our three reports on wound care supplies.

I will provide copies to your committee of those final reports later today and respectfully request, if they could be made part of the record, we would appreciate it.

Senator HARKIN. They will be made a part of the record.

Mr. GROB. Our studies show that Medicare is paying too much for wound care supplies, and these results parallel the results of other studies that we have done on other items of supplies and equipment in the past.

We did not focus on the price differentials in Medicare the way GAO did, but rather simply on whether the items were being properly utilized. You have already summarized the results of our study very well indeed. And the result is pictured over here on this graph.

Senator HARKIN. Go ahead and repeat it. I may have missed something. Go right ahead and tell us again what you found.

Mr. GROB. We took a random sample of 1 percent of claims for wound care supplies earlier this year, and then we used guidelines which were not in effect at the time but were proposed to become effective and became effective yesterday, as a matter of fact.

These utilization guidelines were developed jointly by HCFA with wide consultation of the industry. There were no other guidelines available at the time that we did our report, and we were also anxious to try to predict what the effect of those guidelines would be.

So using those guidelines, over a 9-month period we found $98 million worth of wound care supplies had been billed. And of those, $65 million should not have been paid if the guidelines had been in effect. So about two-thirds of those supplies would not have been paid under the guidelines that went into effect yesterday.

Senator HARKIN. Let me repeat that for emphasis sake. Under the guidelines that just went into effect yesterday—$65 million would not have been paid.

Mr. GROB. Had they been in effect a year ago—would not have been paid out of the $98 million, two-thirds.

Senator HARKIN. And that is just a small claim. How many did you sample?

Mr. GROB. Well, that represents the universe. Two-thirds of the 1-percent sample that we looked at were improper or were questionable. And that translates, when we make our statistical projection, to $65 million total.

Now, you have dramatized in your own testimony the case of excessive bandages. We found similar excesses with regard to, say, hydrogel wound filler, where we found one patient had used 5 gallons of the filler, or had been billed for 5 gallons of the filler, during a 6-month period.

The problem we found was concentrated. Two-thirds of the problem occurred in eight States. Then three-fourths of these questionable billings came from 7 percent of the suppliers in our sample.

Senator HARKIN. Go ahead. I have questions about that point.

Mr. GROB. We also did a parallel study where we surveyed the nursing homes that were involved and the residents of the nursing homes about what was happening. You have mentioned some of the results. Let me just mention a few others for you.

As you said, in 23 percent of the cases, suppliers helped in some way to determine the number of supplies that might need to be ordered.

Another thing that happened was that 45 percent of the patients received the supplies in a kit form. Now HCFA does not pay for kits, but they are still being delivered in that fashion, and we think that presents a risk to the patient. Often these kits contain elements that would not be covered: scissors, gloves, and things of this nature.

And we worry that sometimes the homes are as interested in getting the other supplies as they are the bandages and other dressings that we are paying for.

Someone is asking if we have a kit. This would be an example of a kit. This does not contain all of the supplies we find in kits. This one has no scissors, for example.

But it has quite a few. It has two pair of gloves, a towel, a drape, some gauze pads, sterile saline, which is not covered by Medicare, waste disposal bag, things of that nature.

Senator HARKIN. So what you are saying is the supplier supplies this.

Mr. GROB. Yes.

Senator HARKIN. Medicare pays for the whole thing.

Mr. GROB. Well, Medicare pays what is billed. And what would billed for in this case would be, say, a particular gauze pad or a particular dressing of some sort. And that is what would show up on the bill.

Senator HARKIN. All right.

Mr. GROB. But in fact, it was supplied in this way, so it is hard to say what the dynamics of the underlying economics of the situation is.

Senator HARKIN. Well, maybe I am getting the picture here now. I finally got my little box of bandages here that I got at the drugstore. Now, these little bandages right here, sterile gauze pads, are probably in that box. Check and see if I am right.

Mr. GROB. Well, we have some gauze pads.

Senator HARKIN. Well, these are littler ones than that. Why are these littler?

Mr. GROB. Well, perhaps it depends on the size of the wound.

Senator HARKIN. Well, I guess what I am getting at is—I priced these at the drugstore. These are what I found for 17 cents in Iowa, and this is what HCFA is paying 86 cents for.

So if they are paying that much and they are in the kits, then what you are saying is they are paying for a lot of other things, things that are in there that are boosting the price up. Is that what you are saying?

Mr. GROB. It would seem that that would be the case. Either that or the supplier is losing a lot of money by providing the kits to the nursing homes, which is not likely.

Senator HARKIN. Do you think the supplier is losing a lot of money?

Mr. GROB. I do not believe so. Based on what we have seen here, I do not think so. We think that the fact that it is provided in a kit certainly provides a lot of incentives to bill for more than the patient needs and to provide supplies to the nursing home that it would otherwise have to pay for in some other way.

Senator HARKIN. Yes; I understand.

Mr. GROB. You mentioned that 13 percent of the nursing homes reported being offered various types of incentives. Sometimes they were also apparently receiving misleading information from the suppliers; 11 percent said that Medicare actually requires that the supply be provided in kit form, whereas, in fact, the opposite is the case.

Some of the suppliers would say that saline solution is covered if it is connected with a covered dressing or supply, and that is just not true.

Some 27 percent of the beneficiaries did not recall paying coinsurance and are not aware that they have any insurance that would pay for the coinsurance for the supplies they received.

And 28 percent of the nursing homes said that they were told by the suppliers that beneficiaries would not be billed.

Sometimes the nursing homes are receiving supplies that was not ordered. In 8 percent of the cases, they received supplies that they believed that they did not order.

And a lot of the supplies that is being received in nursing homes is not necessarily being given to the patients for which it was ordered but is basically being stored for use. So in essence, for the billing process, Medicare is paying for stockpiling wound supplies in nursing homes.

About a year ago, we released a report on incontinent supplies. The results were almost identical. On the same chart, in the second pie chart, you see that almost one-half of the $123 million in incontinent supplies were questionable. Again, this was based on a random sample that we drew of bills.

And when we did a survey of nursing homes and the beneficiaries, the answers were almost the same. It was the same litany, almost exactly the same answers back again.

In terms of what to do about the problem, we think that some progress is being made here. The establishment of the specialized

regional carriers by HCFA is a major advancement, and we think that will go a long way to solving the problem.

And of course, the guidelines went into effect yesterday. And with HCFA's computer edits and screens, hopefully we will be well prepared now to prevent paying for some of these bills.

But we believe that something more fundamental is needed in terms of controlling the situation. You mentioned competitive bidding as a possible solution.

And while we did not look at price, we think competitive bidding is also a good way to control the total number of supplies, as well as the price.

The inherent reasonableness authority needs to be extended to the supplies and generally needs to be simplified overall. But we would like to call your attention to what we think is perhaps a more fundamental reform that is needed.

One set of incentives which we believe is not working here is that, for those patients who are in nursing homes, that these items are being billed separately when we probably all would have assumed, if our relatives were in nursing homes, that these items would have been covered in the daily rate.

If a patient goes to a nursing home, there usually is a reason for that. Usually they need help with eating or they might have an incontinence problem or they might have wounds that need tending.

Those would be some of the reasons that patients would be in nursing homes who otherwise would not want to be there.

We would expect that a lot of these supplies would in fact be covered in the daily rate that the nursing home pays. Not for all the supplies, but for many of the supplies, that probably really is the best solution.

With the most sophisticated computers, it is going to be difficult for HCFA and its carriers to control the expenditures for bandages one bandage at a time.

It is not too hard to over-bill for bandages one bandage at a time, but it is awfully hard to review them and to control for them. To us it makes a lot more sense for routine supplies to simply be included in the daily rate.

Senator HARKIN. Well, would that not lead to the same thing? They would just build it into their daily fee. In every nursing home, the fee goes through the roof. We are paying for that in Medicaid anyway.

Mr. GROB. But in this case, one needs to control what the single fee is and not to control the price of every single bandage. There are limits on the fees. It is not open-ended. There are limits in the amount that HCFA pays for the nursing home rates.

So by having——

Senator HARKIN. I am not talking about HCFA. I am talking about Medicaid, title 19.

Mr. GROB. Yes; and even in Medicaid, that is the case, too. The States generally attach limits to what they pay for the daily rate in a State, and those limits are usually premised on an examination of the need for such things as nutrients and incontinence and other kinds of routine supplies.

If they were paid for that way, then the nursing homes would in fact be motivated to do in essence what some of them are doing

now, which is to buy in bulk and to store for use, rather than to buy a bandage for a particular individual.

To some extent, that would be more economical, and their incentive would be to make a bulk purchase that would be cheaper. And they would be concerned about controlling the amount of money they are spending.

Then the nursing facilities would also have a much greater role to play in overseeing the care that is given to the patient.

Right now, the supplier can simply go into a nursing home and can offer to provide supplies and services for patients in the nursing home and basically say to the nursing home, you do not need to worry about it. We will take care of it. We will take care of the supply and service, and we will bill Medicare. You do not need to worry at all.

So to some extent, we believe even the quality of care would be improved for the patient if an arrangement like that were made.

Senator HARKIN. Well, I will take that under advisement. That sounds somewhat reasonable. But I just——

Mr. GROB. It will require some thinking through. We acknowledge that. And I wanted to take the opportunity here today to place that idea on the table. It has not previously, I think, been laid on the congressional table.

Senator HARKIN. No; we have not talked about it.

Mr. GROB. So I thought that sooner or later that ought to be done, and today seemed like a good opportunity to do that.

Senator HARKIN. Well, we will look at it, consider that, but I am going to have to compare that to what I found to be the best cost savings for the Government in just about every case I have looked at in my 20 years here, and that is good old competitive bidding, the good old free market out there.

Mr. GROB. We would be great supporters of that.

Senator HARKIN. Just put it out there and do it on a regional or metropolitan area basis.

Mr. GROB. Yes.

Senator HARKIN. You could put out what we spent last year and say, based on that, give us a bid, and take it from there.

Mr. GROB. We have advocated that in the past and advocate it again.

Senator HARKIN. Well, I had VA, Veterans Administration—I had one bandage that they were paying 4 cents for. HCFA reimbursed it $2.32, the same bandage. Now that is just unconscionable.

Mr. GROB. So we think there are a number of reforms here, and we certainly strongly support the idea of the competitive bidding. And I just wanted to introduce another thought on the table.

Senator HARKIN. Well, it might be. I will look at it. All right. That is interesting. Anything else, Mr. Grob?

PREPARED STATEMENT

Mr. GROB. That concludes my testimony.

Senator HARKIN. All right. Thank you very much.

[The statement follows:]

STATEMENT OF GEORGE GROB

Good morning. My name is George F. Grob, and I am the Deputy Inspector General for Evaluation and Inspections, U.S. Department of Health and Human Services. I am pleased to be here today to discuss fraud and abuse related to medical supplies and equipment in the Medicare program.

Today the Inspector General is releasing three reports on Medicare payments for wound care supplies. We found that as much as $65 million, or two thirds, of the $98 million of bills paid for wound care supplies during a nine month period were questionable. We have found similar problems for other supplies and equipment in the past. Closer oversight using advanced computer screens and targeted reviews can reduce this kind of problem, but a fundamental change in the way Medicare pays for supplies would be better. This might include competitive bidding, streamlining of procedures to reduce payments which are "inherently unreasonable," and consolidating billing for supplies in nursing homes. I believe that the last of these is particularly important and would like to highlight it in my presentation today.

MEDICARE VULNERABILITIES TO FRAUD

Vulnerabilities to fraud and abuse in the Medicare program have been well documented. Most suppliers and providers are honest and dedicated. But because of the huge sums of money being spent--estimated at $177 billion in FY 1995--the Medicare program will always attract individuals or companies that attempt to take advantage of loopholes or violate the law to enrich themselves at the expense of the taxpayer and the Medicare beneficiary.

While I think we have been successful in combating fraud, much more needs to be done. Fraud and abuse permeate all aspects of the program and all areas of the country. But some program areas are more vulnerable than others. Vulnerabilities in three specific program areas -- home health agencies, nursing facilities, and medical equipment and supplies -- have recently been of particular concern to us. This has lead us to undertake Operation Restore Trust, which I will discuss later in this statement.

MEDICAL EQUIPMENT AND SUPPLIES

Durable medical equipment (DME) are items that can withstand repeated use and include oxygen equipment, hospital beds, wheelchairs, transcutaneous electrical nerve stimulators (TENS), seat-lift mechanisms, and other equipment that physicians prescribe for home use. Prosthetics and orthotics are devices that replace all or part of an internal body organ and include leg, arm, back, and neck braces as well as artificial legs, arms, and eyes. Medical supplies include catheter supplies, ostomy supplies, incontinence supplies, and wound care supplies.

We often take a close, hard look at specific items of equipment or supplies when we see a significant increase or radical changes in payments or utilization over a short period of time--which we call "spikes." In the absence of coverage or coding changes, or new medical information about proper use and application of technology, such increases have often been an indication of fraud or inappropriate billings. These spikes have led us to examine claims for seat lift chairs, orthotic body jackets, and, more recently, incontinence supplies.

We also look carefully at items for which changes in coverage policy have been announced or have recently occurred.

We have aggressively pursued those who have defrauded our programs in the area of medical equipment an supplies. In this area alone, our investigations led to 131 successful criminal prosecutions of DME suppliers or their employees between 1990 and 1994. During the same period, we imposed 38 civil money penalties. In the last 2 years alone, we excluded 114 DME companies or their employees from the Medicare and Medicaid programs.

The Congress and the Health Care Financing Administration have taken a number of steps since the late 1980s to curb the abuses in the medical equipment and supplies area. In particular, two reforms deserve prominent mention:

- A fee schedule for DME was implemented in 1989 and the Omnibus Budget Reconciliation Act of 1990 established ceiling and floors to the fee schedules to make payments more uniform.

- In October 1993, HCFA began transferring claims processing for DME from 33 carriers located throughout the country to 4 DME regional carriers (DMERCs). As part of this process, point of sale rules were changed to require suppliers to bill the carrier that serves the jurisdiction where the beneficiary lives. In addition, HCFA required suppliers to apply for new provider numbers and meet certain minimum standards before numbers are issued.

Even with this corrective action, we continue to find problems.

WOUND CARE SUPPLIES

The announcement of new coverage changes, concerns brought to our attention both by the Health Care Financing Administration and the medical supply industry, and our observation of payment and utilization spikes caused us to undertake a study of Medicare payments for wound care supplies.

We are issuing or reports today. There are three: *Questionable Medicare Payments for Wound Care Supplies* (OEI-03-94-00790), *Marketing of Wound Care Supplies* (OEI-03-94-00791), and *Wound Care Supplies: Operation Restore Trust Data* (OEI-03-94-00792). I have made copies available to your staff and would ask that they be made part of the record of this hearing.

Wound care supplies are fillers or protective covers that treat openings on the body caused by surgical procedures, wounds, ulcers, or burns. Wound covers are flat dressing pads. Wound fillers are placed into open wounds to eliminate dead space, absorb exudate, or maintain a moist wound surface. HCFA reimburses for wound care supplies under Medicare Part A through its payments to nursing homes and home health agencies and Medicare Part B through its payments to suppliers. Our reports analyzed payments made under Medicare Part B.

In March of 1994, HCFA broadened its coverage guidelines for wound care supplies (e.g., the previous policy limited coverage to 2 weeks and would only cover surgical procedures performed by a physician). Payments are now based on fee schedules for over 60 codes. The DMERCs issued proposed utilization and medical necessity guidelines in January 1995 which will become effective October 1, 1995.

Medicare Part B Allowances for Wound Care Supplies: 1990 - 1994

There were significant changes in wound care activity between 1990 and 1994. Medicare Part B allowances were as low as $50 million in 1992 and peaked in 1993 at $132 million, an increase of 164 percent. The number of beneficiaries that annually received these supplies ranged from 86,600 in 1993 to as high as 273,300 in 1991. Between 1993 and 1994 the number of Medicare beneficiaries that received wound care supplies increased 47 percent to 127,300. Allowances per beneficiary varied from $199 in 1990 to $1,526 in 1993.

In 1994, 61 percent of the average allowance per beneficiary was for specialty dressings. Medicare allowances for specialty dressings are as high as $35 for large hydrogel wound covers.

Questionable Payments

We drew a random sample of claims from June 1994 through February 1995 and applied proposed DMERC draft guidelines to them. Those claims not meeting the guidelines we labeled as questionable.

It is important to note that the guidelines were not in effect during the period of our review; they will be effective October 1, 1995. However, there were no non-trade associations guidelines available at that time and the draft DMERC guidelines had been developed with industry input. Therefore, we believed they would be the most appropriate ones to use to get an idea of the extent and nature of any payment problems. Furthermore, using them would provide advance intelligence to HCFA regarding the scope of problems it might face when implementing the guidelines this fall.

We found that questionable payments of wound care supplies account for as much as $65 million, or two-thirds of the $98 million in Medicare allowances for the period under review.

While each group of wound care products showed a significant degree of questionable billing, four codes (hydrogel wound filler, tape, a hydrogel dressing wound cover, and a foam dressing wound cover) account for almost half of the excessive utilization.

We found that activity is concentrated in certain States, suppliers, place of service and one carrier. Almost two-thirds of excessive wound care payments were found in 8 States (Puerto Rico, Indiana, New York, California, Illinois, Tennessee, florida, and Louisiana). Three-quarters of excessive payments were made to only 48 suppliers (which represented 7 percent of the suppliers in our random sample). Less than 40 percent of the beneficiaries in our sample resided in skilled nursing or nursing facilities but these beneficiaries received over 70 percent of wound care benefits.

Two Notable Examples

One beneficiary was charged with $5,290 in tape over a 6-month period, almost $5,000 of which appears excessive. This would be enough to purchase 66,000 feet or 12.5 miles of one-inch tape.

Another beneficiary was charged with $11,880 in hydrogel wound filler, $11,533 of which may be unnecessary. This beneficiary's record showed payments for 120 units of one-ounce hydrogel wound filler each month for 6 consecutive months, or over 5 gallons.

Marketing Practices

To assess marketing of wound care supplies, we surveyed a random sample of 420 nursing homes and 469 beneficiaries who received Medicare-reimbursed wound care supplies between June 1994 and February 1995.

We found that nursing homes and physicians determine which patients need supplies but some suppliers determine the amount provided. More than two-thirds of nursing homes report that nurses initially identify a patients need for wound care supplies. However, in 23 percent of the nursing homes the supplier representative decides the number of supplies to be delivered in a given month.

Of great concern, we found that thirteen percent of nursing homes have been offered inducements in exchange for allowing suppliers to provide wound care products to patients in their facility. Twenty-seven percent of beneficiaries said they did not pay coinsurance. In addition, 28 percent of nursing homes have been told by suppliers that wound care supplies will be provided to Medicare beneficiaries at no cost to the patient.

Finally, 11 percent of beneficiaries reported that they used either none or only some of the wound care supplies they received. The majority of nursing homes indicated that they do not have tracking mechanisms to ensure that supplies are used only be the specific beneficiary for which Medicare was billed. In fact, in almost half of nursing facilities, supplies are not identified or marked for use by a specific patient when delivered.

More than half of the beneficiaries reported receiving wound care supplies in kit form. While Medicare does not reimburse wound kits, certain component parts may be separately billed to Medicare. As of October 1, 1995, Medicare will no longer reimburse any supplies if they are

provided as part of a kit. Medicare policy will be that the supplies need to be tailored to the specific needs of an individual patient and this can not be accomplished when supplies are provided in standard kit form.

Investigations

Our office has opened 11 cases related to wound care supplies since 1990. While five cases remain open, three cases have resulted in convictions or settlements:

- The owner of one company was convicted and sentenced for selling the names of Medicare beneficiaries, along with the supplies his company had provided, to a Connecticut durable medical equipment company. The Connecticut company, used the lists to submit claims to the Medicare carrier for items he never provided and which had already been submitted and paid by the carrier for the States in which the beneficiaries had resided. The owner of the first company was sentenced to 26 months, 3 years probation, and to repay $75,000. His company was fined $10,000. The owner of the second company was sentenced to 24 months, 3 years probation, and to repay $300,000. His company was fined $1000. In November 1994, this second company consented to a civil judgement of $4,955,000.

- Another company was convicted for billing the Pennsylvania carrier for wound care supplies for beneficiaries living outside of the carrier's geographic region to receive a higher reimbursement.

- A family and their two companies paid a $1.5 million settlement and relinquished over $465,000 held in escrow by the Pennsylvania Medicare carrier. Salesmen throughout the Midwest identified Medicare beneficiaries who appeared qualified for durable medical equipment; the companies then billed the Pennsylvania carrier, who had a high reimbursement for wound care kits.

INCONTINENCE SUPPLIES

Last Fall, we issued two reports on Medicare payments for incontinence supplies. In large part, our findings parallel those I've just discussed for wound care supplies.

Incontinence supplies are used for individuals who have bladder or bowel control problems. Medicare reimbursement for these supplies is provided under Medicare's coverage of prosthetic devices which replace all or part of a permanently inoperative or malfunctioning body organ. Coverage is allowed when incontinence is of long and indefinite duration. Incontinence supplies include catheters and external collection devices such as pouches or cups. Catheters are flexible, tubular instruments used to control urinary flow. The HCFA will also reimburse for accessories that aid in the effective use of such devices, such as drainage bags, irrigation syringes, sterile saline solutions and lubricants. However, certain items, such as absorbent undergarments or diapers, are specifically excluded from Medicare coverage.

Medicare allowances for incontinence supplies more than doubled in 3 years despite a drop in the number of beneficiaries using these supplies. The amount allowed rose from $88 million in 1990 to $230 million in 1993, an increase of $142 million. During the same period, the number of beneficiaries receiving incontinence supplies fell from 312,000 to 293,000, causing the allowance per beneficiary to increase from $282 to $786, a 179 percent increase.

We believe that questionable billing practices may account for almost half of incontinence allowances in 1993. Approximately $88 million was allowed for accessories that were not billed along with a catheter or collection device, indicating that coverage guidelines were not met. Most of these payments were for just three supplies--sterile saline irrigation solution, syringes, and lubricant. Another $19 million in allowances were made for catheters or devices that appeared to be excessive

in number. Together these questionable allowances amounted to $107 million in 1993. If left unchecked, the cost to Medicare will be $535 million over the next five years. Most of these payments were concentrated in one carrier and a small number of suppliers and beneficiaries.

Information from nursing facilities indicates that suppliers engage in questionable marketing practices to increase their business in incontinence supplies. Twenty-four percent of nursing facilities have reported that supplier representatives decided the number of supplies to be delivered in a given month to beneficiaries. In addition, nursing facilities have reported other practices by suppliers such as the routine waiving of beneficiary coinsurance payments as well as offers of inducements in exchange for allowing suppliers to provide incontinence supplies to patients.

We are about to release a report entitled *Medicaid Payments for Incontinence Supplies* (OEI-03-94-00771) in which we found that half of the States in our sample had encountered improper billings for incontinence supplies under the Medicaid program similar to those we had found in Medicare. In one State, California, improper payments exceeded $100 million. Other States experienced problems, but to a lesser degree. We also found a significant problem with claims paid by Medicare for which Medicaid pays coinsurance and deductibles (for beneficiaries dually eligible for both Medicare and Medicaid). Not surprisingly, when State Medicaid agencies make such payments, they generally do not review the appropriateness or necessity of the claim paid by Medicare. In addition, Medicare does not require its carriers to notify Medicaid State agencies of improper payments that have been made on behalf of Medicaid beneficiaries. Thus, States may inadvertently make unallowable payments for the Medicare copayments. We recommended that HCFA alert Medicaid State agencies about this vulnerability and take appropriate steps to ensure that States are notified of improper Medicare payments which contractors discover have been made on behalf of a Medicaid beneficiary.

Investigation

As a result of our concerns in this area, we have initiated several national investigations of DME companies which supply incontinence care, urological, and orthotic items to patients in nursing homes and long-term care facilities. In the first prosecutive action under this initiative, a former employee of a Tennessee-based equipment company pled guilty in Massachusetts to conspiracy to defraud Medicare in a multi-million-dollar fraud scheme. The company billed for items sold as far away as California and Florida. It engaged in "carrier shopping," determining the States in which carriers paid the highest Medicare reimbursement and using shell offices or mail drops to create the illusion that its supplies were sold in those States. It also billed for supplies never provided, including supplies for deceased nursing home patients. The company has filed millions of dollars in fraudulent claims across the country, including $4.4 million in Massachusetts alone. Eight other employees are expected to be indicted.

CORRECTIVE ACTION STILL REQUIRED

I had previously noted recent, important reforms in Medicare's system for paying for equipment and supplies. The consolidation of carrier oversight in the four DMERCs is a most significant improvement which holds great promise for reducing unnecessary payments. This initiative of HCFA's is responsive to many recommendations which we have made in the past.

With regard to wound care supplies, I have already mentioned that the guidelines which we used in our study to review Medicare payments went into effect yesterday. With proper computer edits in place and by using focused reviews where aberrant payments are found, the DMERCS will be able to prevent many of the abuses which we uncovered in our studies.

Nevertheless, with all the progress we have made, I believe that even more fundamental reforms are needed in the way Medicare pays for equipment and supplies. Here is what we recommend.

Authorize Competitive Bidding

HCFA does not have the statutory authority which would allow it to take advantage of its marketplace position to obtain discounts through competitive bidding. While competitive bidding is not appropriate for every aspect of the Medicare program, we believe that it can be used effectively in many areas. Competitive bidding would allow HCFA to contract with specific providers to deliver a fixed number of items and services to Medicare beneficiaries in specific geographic locations at a fixed price.

Broaden and Streamline the Secretary's Authority to Reduce Inherently Unreasonable Payment Levels

In a competitive health care market, prices will change. In general, even when the OIG or HCFA identifies a particular piece of equipment as significantly overpriced (i.e., as "inherently unreasonable"), the Department or carriers cannot adjust reimbursement levels without going through a regulatory process which is resource intensive and time consuming process. It can take from 2 to 4 years. The only other alternative is for the Congress to legislatively reduce the payment amount. We recommend that the Congress enact legislation to give HCFA and its carriers much greater flexibility in reducing payments based on simple market surveys.

Require Consolidated Billing for Nonprofessional Services Provided to Nursing Home Residents

We believe that a long-term solution to some of the abuses we have found associated with wound care and incontinence supplies in nursing homes is to consolidate (sometimes called "bundling") billing for the supplies with the bill for the overall daily care rate of the nursing home. This only makes sense. Nutrition, incontinence supplies, and routine wound care are part of what nursing homes are supposed to do. These routine supplies and services should not be separately charged outside the daily rate.

There are a number of reasons why we are concerned about the provision of services and equipment to beneficiaries in nursing facilities by a multiplicity of providers. First and foremost, this can jeopardize the quality of care which a patient receives. No single individual or institution is held responsible for managing the beneficiary's total care.

From the point of view of economy and efficiency, this system provides no incentive for ensuring that only needed services are delivered to the patient. Indeed, many of the incentives run in quite the opposite direction.

We found that in 1992 Medicare allowed more than $4.2 billion services provided to residents of nursing homes. Medicare paid $2.7 billion of this; the beneficiaries were charged for the remaining $1.5 billion.

Our studies indicate that substantial savings could result if these items were purchased by the nursing facility, acting as a prudent purchaser and taking advantage of discounts, rather than being billed to Part B and reimbursed under fee schedules.

Finally, this method of payment would overcome many the control issues HCFA faces under the control system. HCFA and its carriers should not be paying millions of dollars for bandages one at a time. No matter how good its computer screens and codes are, abusive billings will go undetected. You and I do not buy bandages that way. We buy them by the box when they are on sale and store them for future use. HCFA ought to expect that nursing homes will do the same. When we help our relatives and friends enter a nursing home it is because they need help with routine living activities or with routine medical care. We expect that they will be fed, that they will be assisted with their incontinence problems, and that simple wounds will be dressed. That is what we think we are paying for. We should not be billed separately for such routine care. And neither should the Medicare program.

OPERATION RESTORE TRUST

Until major reforms are enacted, we are doing everything we can within our limited resources to methodically identify and eradicate fraud and abuse in the Medicare program. One of our major initiatives is Operation restore Trust. The OIG is working jointly with HCFA and the Administration on Aging (AoA) on a project designed to prevent and detect fraud and abuse in three rapidly growing sectors of the health care industry: home health agencies, nursing facilities and durable medical equipment suppliers. Operation Restore Trust, announced by the President on May 3, 1995, is a 2-year partnership of Federal and State agencies working together to protect the health care trust funds more effectively through shared intelligence and coordinated enforcement, and to enhance the quality of care for the programs' beneficiaries. The project has initially targeted five States (California, Florida, Illinois, Texas, and New York) which together account for 40 percent of the Nations' Medicare and Medicaid beneficiaries.

We have assembled teams that include investigators from our Office of Investigations and the States' Medicaid Fraud Control Units; auditors and evaluators from both the OIG and HCFA; quality assurance specialists from the State surveyors and durable medical equipment regional coordinators; State long-term care ombudsmen through AoA; and prosecutors from the Department of Justice and the Offices of the United States Attorneys General. These teams are conducting financial audits of providers, criminal investigations and referrals to Federal and State prosecutors, civil and administrative sanctions and recovery actions, and surveys and inspections of nursing facilities. The collective experience of these teams also will be used to recommend to HCFA and the Congress program adjustments to prevent future fraud and to reduce waste and abuse.

A hot line (1-800-HHS-TIPS) has been established to receive allegations of fraud and abuse on a confidential basis. To further assist health care providers, the OIG will continue its practice of issuing Special Fraud Alerts to identify and describe fraudulent and abusive health care practices. Moreover, a voluntary disclosure program has been initiated on a pilot basis under the auspices of Operation Restore Trust. Through this pilot program, the OIG and the Department of Justice have established procedures by which home health and nursing facility suppliers and providers in the five States may come forward with full disclosure of potential fraud and abuse. By doing so, self-disclosing providers may minimize the cost and disruption of an investigation, negotiate a monetary settlement in lieu of prosecution, and possibly avoid exclusion from Medicare and Medicaid program participation when appropriate.

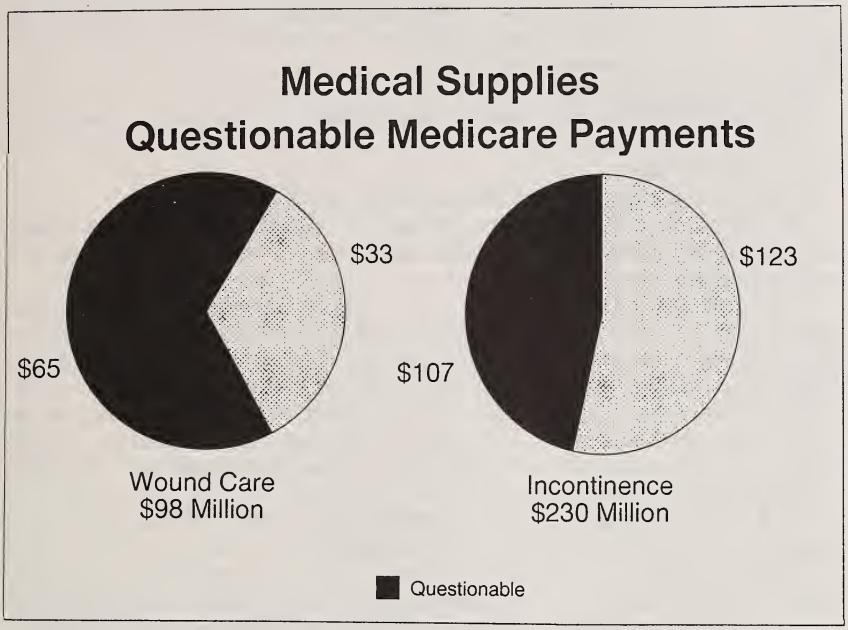
STRONGER ANTI-FRAUD AUTHORITIES NEEDED

Operation Restore Trust will take 2 years for completion and evaluation. If it proves to be both effective and efficient, other areas may be singled out for similar treatment. Employing these and other initiatives, we are working to ensure the integrity and efficiency of the Medicare and Medicaid programs and to protect the beneficiaries of those programs.

But we do not need to wait until Operation Restore Trust has run its course to know that stronger anti-fraud authorities are needed. We need a permanent program to coordinate Federal, State, and local law enforcement, audit, and evaluation efforts. We need stronger statuary language and penalties that can be applied to those who would defraud the Medicare program. And we need resources. We know that the Federal deficit needs to be reduced. Our proven track record of returning savings many times greater than resources we consume give us confidence that we can help pull the deficit down while protecting Medicare and Medicaid beneficiaries. We strongly recommend the enactment of a reinvestment authority which would allow fines and penalties imposed recovered from those who defraud Medicare and Medicaid to be recycled for use in our fight against crime and abuse. Several bills which provide authorities like these are now pending before the Congress. We urge their enactment.

CONCLUSION

I appreciate the opportunity to appear before you today and to share with you some of our concerns and work we have done in the Medicare program. I look forward to sharing the results of our Operation Restore Trust activities as well as other activities undertaken by our office.



MEDICARE PAYMENTS

Senator HARKIN. Let me just run through some questions here on the record for both Mr. Ratner and you.

Mr. Ratner, this subcommittee held a hearing last year in April, April 22 last year, that highlight the problems with Medicare payments for surgical dressings, 1½ years ago.

After that hearing, my staff was informed by HCFA that no payments would be made under the newly expanded benefit until appropriate safeguards were in place. Here is the letter right here, May 13, 1994, addressed to Peter Reinecke, my legislative director.

It says here: "By June 1"—I will not read the whole thing, but it says:

> By June 1, 1994, the DMERC's will implement medical review screens for selected items that are high cost or potentially subject to abuse. These screens will identify claims exceeding a specified number of services per month per beneficiary. There will be screens for both primary and secondary dressings. The DMERC's have identified those items they believe are most subject to over-utilization and believe that these screens will identify those items where excessive services, and thus dollars, are claimed.

Based on your work, were adequate safeguards in place before Medicare began paying these claims?

Mr. RATNER. No.

Senator HARKIN. Are the safeguards—have you looked at the safeguards they put in place yesterday? Do you consider those to be adequate safeguards?

Mr. RATNER. Those just were put in place. We have not done a review of them.

Senator HARKIN. So you cannot say about that.

Now I ask the Inspector General's Office the same question: Based on your work, were adequate safeguards in place before Medicare began paying the claims?

Mr. GROB. Apparently not.

Senator HARKIN. And have you looked at the new safeguards that were put in yesterday?

Mr. GROB. Yes.

Senator HARKIN. Do you believe those will?

Mr. GROB. I think they can be used to significantly reduce unauthorized payments if the associated computer codes and edits are put into place as well.

I am not optimistic that we will be able to prevent all the overutilization for the reasons I mentioned before. It happens just too many times, too many bills, too many items. And even with the best computers, I think there are going to be some problems there.

With the computer codes and computer edits, there should be some improvement here. One reason is that the utilization guidelines are very, very specific, and so they lend themselves very well to computerized techniques.

So I would hope for some progress but still would prefer the broader reforms that we discussed earlier.

Senator HARKIN. Mr. Grob, based on the inspector general's review and knowing that Medicare paid claims under the expanded wound care benefit for 1½ years without appropriate medical policies to limit reimbursement, could you estimate how much Medicare lost to questionable payments over this period?

I might just add that in our hearings in April of last year, HCFA said that the first year cost to Medicare of this benefit expansion would be $10 million. Was that accurate?

Mr. GROB. No; what we looked at was a 9-month period in which the total bills for that period were $98 million.

Senator HARKIN. Just for the expanded benefit.

Mr. GROB. Oh, just for the expanded benefit. Well, we were not able to distinguish the expanded from the regular benefit. I am sorry.

Senator HARKIN. I see.

Mr. GROB. Because a lot of these—well, that is right. Those details were just too detailed for us to look at. We simply looked at how well the thing would work. So during the 9-month period, $98 million was spent and two-thirds were unallowed or were questionable.

Senator HARKIN. The whole thing, $60 million.

Mr. GROB. So it is hard to predict right now. We tried to predict what the payments would be next year, for example, but the Medicare payments for wound care supplies have been fluctuating quite a bit over the last 4 or 5 years. Policies have been in a State of flux. So we were not able to determine a trend.

If that is a 9-month period, and you said a year and a half, you could double it, I suppose, as a very rough estimate.

Senator HARKIN. Yes; I am just trying to figure out again, HCFA said the first year cost to Medicare of the expansion. There was a benefit expansion that they said would be about $10 million for a year.

I am trying to extrapolate, but there is no way we can get a handle on that. Is that what you are saying?

Mr. GROB. We were unable to do that, because the coverage provisions have fluctuated so much in the last several years and the practice is so much—in fact, in our report there is a table in there that illustrates the fluctuation and uncertainty in the amounts.

We were unable to detect a particular trend. We did not even want to venture to estimate what it would be in the future.

But just in terms of totals, we see the two-thirds numbers for a 9-month period. A very rough guess might have been twice that in a year and a half, but that is—we are making rough guesses now, and we need to say so.

Senator HARKIN. I see; your report indicated that 13 percent of nursing homes questioned had received inducements ranging from free trial products to cameras, blenders, diamond rings. Would these inducements constitute kickbacks under current Medicare law?

Mr. GROB. Yes; they would. Now, the way we do these surveys, we ask people if they were offered inducements, and that is what they answered, yes, that they were offered inducements.

Senator HARKIN. Is it illegal for a supplier to offer that inducement?

Mr. GROB. I believe yes, it would be.

Senator HARKIN. Has anyone to your knowledge ever been prosecuted of these that you asked about?

Mr. GROB. These particular ones, no. We have not referred these cases to our investigators. We could conceivably have them look at these. These were basically relatively small cases, but we can do that.

When we do these surveys, we try to do it in such a way that the people answering will be forthcoming with the answers to the questions, because it helps us get a better sense of the overall problem.

Senator HARKIN. The other thing I just found mind-boggling was that in 23 percent of the nursing homes, the supplier determined the number of supplies to be delivered. That is one out of almost four. Is this allowable under current Medicare rules?

Mr. GROB. I would say it probably is allowable under current Medicare rules.

Senator HARKIN. It is, to allow the supplier to determine how much somebody ought to have?

Mr. GROB. The supplier would come in and, if you will, help the nursing home make that determination. The need for the wound care supply would be set by a doctor, say, or by a nurse, for that particular item. But once that is the case, the proper number of supplies need to be ordered.

I suppose that the supplier industry could say that their suppliers provide a service of offering technical advice and assistance to the different people who use the wound care supplies. We are very nervous about this, obviously.

Senator HARKIN. Explain something to me, maybe you or Mr. Ratner. It was in your testimony, but Mr. Ratner's GAO found this also.

One beneficiary was charged with $5,290 in tape, tape, this roll of tape here, over a 6-month period, almost $5,000 of which appears excessive. This would be enough to purchase 66,000 feet or 12.5 miles of 1-inch tape.

Mr. GROB. Yes; that was in our testimony.

Senator HARKIN. Well, OK. If the beneficiary was charged that, was that charged by the nursing home or the supplier?

Mr. GROB. The supplier charged that. That is correct.

Senator HARKIN. Now this was a nursing home, right?

Mr. GROB. Yes.

Senator HARKIN. Was it in a nursing home?

Mr. GROB. I believe that was in a nursing home. Well, we are not sure that one was in a nursing home, but that would be the typical situation. This is part of the reason I mentioned our proposal about the daily rate. The suppliers basically are doing the billing for these supplies. These bills are not coming from the nursing homes. They are coming from the suppliers.

Senator HARKIN. Well, you found some of this, right, Mr. Ratner, at GAO? I guess what I cannot understand is if I am operating a nursing home and I have a patient in this nursing home and there are just suppliers supplying tape, certainly would I not know whether or not they were using 12.5 miles of tape in a 6-month period of time, as the nursing home operator? Nobody checks on this stuff?

Mr. RATNER. The question really is, in part: Who has the financial incentive to do so? And the second is: At what level, even within a nursing home, does that knowledge reside?

There may well be someone in the nursing home who is aware that a patient is getting a certain amount of tape, that a certain amount of tape is actually arriving for that patient.

The question is whether there is any financial incentive to do anything with that knowledge. And under many billing schemes, the answer is no.

Mr. GROB. That is basically what I see is the crux of the problem, that the nursing home does not have an incentive, necessarily, to worry about whether the supplies are correct.

Basically the supplier says, "Do not worry. We will take care of it for you. We will take care of the billing. You do not need to worry."

Senator HARKIN. Have either one of you looked into this practice, the supplier—it just seems to me that this has tremendous incentive for abuse. And if at this point I am unable to determine how much supplies—should that practice not be stopped?

Mr. GROB. Senator, that was our point in raising it, which is whether or not it is legal or not legal. It certainly does provide an incentive for abuse and waste.

Mr. RATNER. I would just add that we have a report that we hope will be coming out shortly that focuses on the extent to which nursing home residents are vulnerable targets for abusive schemes or just practices that really should not be going on. So yes, this is a significant issue.

Senator HARKIN. What kind of led me into this over 1½ years ago, almost 2 years now, is a constituent of mine in Atlantic, Iowa,

had written me and sent me a copy of a reimbursement for Medicare for her mother-in-law who was in a nursing home.

It was for bandages, and it came to several thousand dollars, $5,000 over a few weeks period of time, and she questioned it.

We began to look into it, and the more we looked into it, that sort of led to the basis of the hearing that we had 1½ years ago. What we found was that the supplies originated from Pennsylvania.

The nursing home did not even know this. The supplier who put in for the reimbursement was out of Pennsylvania. The nursing home is in a small town in western Iowa. They had no knowledge of this. But evidently the billing that came to the mother or the daughter that got the billing saw that.

Now again, there was no financial incentive for her to bring this to my attention other than she was just a good citizen and said, "There is something wrong here."

But if this is a prevalent practice, where some company, who is a supplier in one State, is billing for things that are going on in another State, then I can understand why the nursing home may not know a thing about it.

Mr. RATNER. Well, I think that may be part of the problem. We should note that some of the problems were worse when you did not have the regional carriers, the DMERC's, and suppliers could do shopping for carriers that would be the easiest targets for getting these things through.

Senator HARKIN. Now, I hear all these great things about the DMERC's. They came in how long ago? When did the DMERC's start?

Mr. GROB. October of 1993, so 2 years ago.

Senator HARKIN. October 1993, about 2 years now. I hear all these great things, but all this stuff we are talking about took place with the DMERC system in existence.

Mr. GROB. Well, I think the point is that while this improved things, there are still some real problems.

Senator HARKIN. Boy, if this is an improvement, it must have really been bad.

Mr. GROB. Yes; that is true.

Senator HARKIN. This is a shock. I have been at this 5 years, and I am still astounded by this. I am going to ask Mr. Vladeck about the DMERC's because I hear these great things, but I just point out again that what we are finding is taking place with the DMERC's being in existence. So something is not working right.

Just a couple more questions. Mr. Ratner, the GAO has recommended that HCFA require all medical supply bills to be itemized in order to reduce unnecessary payments. HCFA rejected this recommendation saying it would not be worth it. What is your response to that?

Let me follow up with one more question. As I understand it, when you went in to look at these billings, this sampling you got, it was under code 270. But you were able to get an itemized account, right? You got the itemized account.

Mr. RATNER. We were able to ask the contractor to go back and request documentation. And then, in a number of cases, that documentation was provided with the itemized data. Yes.

Senator HARKIN. Why can HCFA not do that? Again, I am just wondering why—the GAO made this recommendation. They said they cannot do it. Is there any reason that you know of why they could not request itemized accounts?

Mr. RATNER. We think that it would be a good idea to do this. We think that it is done on the part B side now already and that, indeed, as you point out, the providers usually have such data.

I think HCFA says that they have a concern about a burden being placed on particular providers, particularly home health agencies. Our response is that, while it is certainly true that accurate billing does create an administrative cost and while you can get absurd situations with efforts being placed on somebody to go for one little gauze pad, nonetheless, how do we know that—under even some broader payment scheme—things are being done properly without having some itemized backup?

What in fact are they ordering? Are there no records at all by providers?

We think that really, while the administrative issue needs to be dealt with seriously, this is a feasible thing.

Senator HARKIN. Because the universe is not unlimited in terms of the item. I mean, there are just so many items.

Obviously, there are a lot of different items, but it would seem to me that there is a certain set universe of items that you could list. And with that and computer checks and things, you could find out just what they were paying for.

I was astounded when I found in your investigation that under one code 270 for medical supplies, there was $20,000-some for a pacemaker that should not have been in there. This is for bandages and things like that.

Mr. RATNER. True.

Senator HARKIN. One last thing. Talking about the part A and part B, about finding these duplicate claims, GAO's report pointed this out, also, about these missed payments, you recommended a fix to this. What has HCFA done to respond to that recommendation, do you know?

Mr. RATNER. Well, I think they point to the existence of the common working file and the ability to make some cross-checks now for other items and they point to the future with the Medicare transaction system, which certainly augers—either augers well or offers great hope for improvements here.

But in this particular thing, the stumbling block is on the part A side in itemizing. And here, we have a difference of opinion.

Senator HARKIN. One last item, Mr. Grob. As I mentioned in my opening statement, I asked Ms. Brown, the outstanding inspector general for HHS, to evaluate the fraud and abuse provisions of the Medicare bill, the only one we have before us now, which is the House bill that came out of the House Ways and Means Committee.

I was very concerned about several changes I thought could result in even greater Medicare fraud. Inspector General Brown's response to me, which I would ask to be included in the hearing record at this point, confirmed my concerns.

It is quite a lengthy letter, but basically—here it is. I just want to read this one sentence. H.R. 2389, which is the House bill, she said:

> However, if enacted, certain major provisions of H.R. 2389 would cripple the efforts of law enforcement agencies to control health care fraud and abuse in the Medicare Program and to bring wrongdoers to justice.

Do you share these concerns, Mr. Grob?

Mr. GROB. Yes; of course I do.

Senator HARKIN. I look to the letter, and I found the different provisions there in terms of kickbacks, raising the threshold for proof——

Mr. GROB. Yes; if you wish, I could——

Senator HARKIN. I would just state here that what she said was, "For the vast majority of the present day kickback schemes, the proposed amendment would place an insurmountable burden of proof on the Government."

Do you share that?

Mr. GROB. Yes.

Senator HARKIN. I want to make that a part of the record.

[The letter follows:]

LETTER FROM JUNE GIBBS BROWN, INSPECTOR GENERAL

The Honorable Tom Harkin
United States Senate
Washington, D.C. 20510

SEP 29 1995

Re: H.R. 2389: "Safeguarding Medicare Integrity Act of 1995"

Dear Senator Harkin:

You requested our views regarding the newly introduced H.R. 2389, which we understand may be considered in the deliberations concerning the "Medicare Preservation Act." We strongly support the expressed objective of H.R. 2389 of reducing the fraud and abuse which plagues the Medicare program. The proposed legislation contains some meritorious provisions. However, if enacted, certain major provisions of H.R. 2389 would cripple the efforts of law enforcement agencies to control health care fraud and abuse in the Medicare program and to bring wrongdoers to justice.

The General Accounting Office estimates the loss to Medicare from fraud and abuse at 10 percent of total Medicare expenditures, or about $18 billion. We recommend two steps to decrease this problem: strengthen the relevant legal authorities, and increase the funding for law enforcement efforts. Some worthy concepts have been included in H.R. 2389, and we support them. For example, we support:

- a voluntary disclosure program, which allows corporations to blow the whistle on themselves if upper management finds wrongdoing has occurred, with carefully defined relief for the corporation from qui tam suits under the False Claims Act (but not waiver by the Secretary of sanctions);

- minimum periods of exclusion (mostly parallel with periods of exclusion currently in regulations) with respect to existing exclusion authorities from Medicare and Medicaid; and

- increases in the maximum penalty amounts which may be imposed under the civil monetary penalty laws regarding health care fraud.

As stated above, however, H.R. 2389 contains several provisions which would seriously erode our ability to control Medicare fraud and abuse, including most notably: making the civil monetary penalty and anti-kickback laws considerably more lenient, the unprecedented creation of an advisory opinion mechanism on intent-based statutes, and a trust fund concept which would fund only private contractors (not law enforcement). Our specific comments on these matters follow.

1. **MAKING CIVIL MONETARY PENALTIES FOR FRAUDULENT CLAIMS MORE LENIENT BY RELIEVING PROVIDERS OF THE DUTY TO USE REASONABLE DILIGENCE TO ENSURE THEIR CLAIMS ARE TRUE AND ACCURATE.**

Background: The existing civil monetary penalty (CMP) provisions regarding false claims were enacted by Congress in the 1980's as an administrative remedy, with cases tried by administrative law judges with appeals to Federal court. In choosing

the "knows or should know" standard for the mental element of the offense, Congress chose a standard which is well defined in the Restatement of Torts, Second, Section 12. The term "should know" places a duty on health care providers to use "reasonable diligence" to ensure that claims submitted to Medicare are true and accurate. The reason this standard was chosen was that the Medicare system is heavily reliant on the honesty and good faith of providers in submitting their claims. The overwhelming majority of claims are never audited or investigated.

Note that the "should know" standard does not impose liability for honest mistakes. If the provider exercises reasonable diligence and still makes a mistake, the provider is not liable. No administrative complaint or decision issued by the Department of Health and Human Services (HHS) has found an honest mistake to be the basis for CMP sanction.

H.R. 2389 Proposal: Section 201 would redefine the term "should know" in a manner which does away with the duty on providers to exercise reasonable diligence to submit true and accurate claims. Under this definition, providers would only be liable if they act with "deliberate ignorance" of false claims or if they act with "reckless disregard" of false claims. In an era when there is great concern about fraud and abuse of the Medicare program, it would not be appropriate to relieve providers of the duty to use "reasonable diligence" to ensure that their claims are true and accurate.

In addition, the bill treats the CMP authority currently provided to the Secretary in an inconsistent manner. On one hand, it proposes an increase in the amounts of most CMPs which may be imposed under the Social Security Act. Yet, it would significantly curtail enforcement of these sanction authorities by raising the level of culpability which must be proven by the Government in order to impose CMPs. It would be far preferable not to make any changes to the CMP statutes at this time.

2. MAKING THE ANTI-KICKBACK STATUTE MORE LENIENT BY REQUIRING THE GOVERNMENT TO PROVE THAT "THE SIGNIFICANT" INTENT OF THE DEFENDANT WAS UNLAWFUL.

Background: The anti-kickback statute makes it a criminal offense knowingly and willfully (intentionally) to offer or receive anything of value in exchange for the referral of Medicare or Medicaid business. The statute is designed to ensure that medical decisions are not influenced by financial rewards from third parties. Kickbacks result in more Medicare services being ordered than otherwise, and law enforcement experts agree that unlawful kickbacks are very common and constitute a serious problem in the Medicare and Medicaid programs.

The two biggest health care fraud cases in history were largely based on unlawful kickbacks. In 1994, National Medical Enterprises, a chain of psychiatric hospitals, paid $379 million for giving kickbacks for patient referrals, and other improprieties. In 1995, Caremark, Inc. paid $161 million for giving kickbacks to physicians who ordered very expensive Caremark home infusion products.

Most kickbacks have sophisticated disguises, like consultation arrangements, returns on investments, etc. These disguises are hard for the Government to penetrate. Proving a kickback case is difficult. There is no record of trivial cases being prosecuted under this statute.

H.R. 2389 Proposal: Section 201 would require the Government to prove that "the significant purpose" of a payment was to induce referrals of business. The phrase "the significant" implies there can only be one "significant" purpose of a payment. If so, at least 51 percent of the motivation of a payment must be shown to be unlawful. Although this proposal may have a superficial appeal, if enacted it would threaten the Government's ability to prosecute all but the most blatant kickback arrangements.

The courts interpreting the anti-kickback statute agree that the statute applies to the payment of remuneration "if one purpose of the payment was to induce referrals." United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985) (emphasis added). If payments were intended to induce a physician to refer patients, the statute has been violated, even if the payments were also intended (in part) to compensate for legitimate services. Id. at 72. See also: United States v. Kats, 871 F.2d 105, 108 (1989); United States v. Bay State Ambulance, 874 F.2d 20, 29-30 (1st. Cir. 1989).

The proposed amendment would overturn these court decisions.

However, the nature of kickbacks and the health care industry requires the interpretation adopted by Greber and its progeny. To prove that a defendant had the improper intent necessary to violate the anti-kickback statute, the prosecution must establish the defendant's state of mind, or intent. As with any intent-based statute, the prosecution cannot get directly inside the defendant's head. The prosecution must rely on circumstantial evidence to prove improper intent. Circumstantial evidence consists of documents relevant to the transaction, testimony about what the defendant said to business associates or potential customers, etc. These types of evidence are rarely clear about the purposes and motivations of the defendant. The difficulties of establishing intent are multiplied by the complexity, size, and dynamism of the health care industry, as well as the sophistication of most kickback scheme participants. Documents are "pre-sanitized" by expert attorneys. Most defendants are careful what they say. In most kickback prosecutions, the Government has a difficult task to prove beyond a reasonable doubt that even one purpose of a payment is to induce referrals.

If the Government had to prove that inducement of referrals was "the significant" reason for the payment, many common kickback schemes would be allowed to proliferate. In today's health care industry, very few kickback arrangements involve the bald payment of money for patients. Most kickbacks have sophisticated disguises. Providers can usually argue that any suspect payment serves one or more "legitimate purposes." For example, payments made to induce referrals often also compensate a physician who is providing health care items or services. Some payments to referral sources may be disguised as returns on investments. Similarly, many lease arrangements that indisputably involve the bona fide use of space incorporate some inducement to refer in the lease rates. In all of these examples, and countless others, it is impossible to quantify what portions of payments are made for nefarious versus legitimate purposes.

Where the defendant could argue that there was some legitimate purpose for the payment, the prosecution would have to prove beyond a reasonable doubt, through circumstantial evidence, that the defendant actually had another motive that was "the significant" reason. For the vast majority of the present-day kickback schemes, the proposed amendment would place an insurmountable burden of proof on the Government.

3. CREATION OF AN EASILY ABUSED EXCEPTION FROM THE ANTI-KICKBACK STATUTE FOR CERTAIN MANAGED CARE ARRANGEMENTS.

Background: There is great variety and innovation occurring in the managed care industry. Some managed care organizations, such as most health maintenance organizations (HMOs) doing business with Medicare, consist of providers who assume financial risk for the quantity of medical services needed by the population they serve. In this context, the incentive to offer kickbacks for referrals of patients for additional services is minimized, since the providers are at risk for the additional costs of those services. If anything, the incentives are to reduce services. Many other managed care organizations exist in the fee for service system, where the traditional incentives to order more services and pay kickbacks for referrals remain. In the fee for service system, the payer (like Medicare and private insurance plans) is at financial risk of additional services, not the managed care organization. While broad protection from the anti-kickback statute may be appropriate for capitated, at-risk entities like the HMO described above, such protection for managed care organizations in the fee for service system would invite serious abuse.

H.R. 2389 Proposal: Section 202 would establish broad new exceptions under the anti-kickback statute for "any capitation, risk-sharing, or disease management program." The lack of definition of these terms would result in a huge opportunity for abusive arrangements to fit within this proposed exception. What is "risk-sharing?" Is not any insurance a form of risk sharing? What is a "disease management program?" Does not that term include most of health care?

Nefarious organizations could easily escape the kickback statute by simply rearranging their agreements to fit within the exception. For example, if a facility wanted to pay doctors for referrals, the facility could escape kickback liability by establishing some device whereby the doctors share in the business risk of profit and loss of the business (i.e., they would share some risk, at least theoretically). Then, the organization could pay blatant kickbacks for every referral with impunity.

If the concern is that the kickback statute is hurting innovation, as observed above, there is now an explosion of innovation in the health care industry, especially in managed care. No one in Government is suggesting that HMOs or preferred provider arrangements, etc., formed in good faith, violate the kickback statute. There has never been any action against any such arrangement under the statute.

4. INAPPROPRIATE EXPANSION OF THE EXCEPTION TO THE ANTI-KICKBACK STATUTE FOR DISCOUNTS.

Background. Medicare/Medicaid discounts are beneficial and to be encouraged with one critical condition: that Medicare and/or Medicaid receive and participate fully in the discount. For example, if the Medicare reasonable charge for a Part B item or service is $100, Medicare would pay $80 of the bill and the copayment would be $20. If a 20 percent discount is applied to this bill, the charge should be $80, and Medicare would pay $64 (80 percent of the $80) and the copayment would be $16. If the discount is not shared with Medicare (which would be improper), the bill to Medicare would falsely show a $100 charge. Medicare would pay $80, but the copayment would be $0. This discount has not been shared with Medicare.

Many discounting programs are designed expressly to transfer the benefit of discounts away from Medicare. The scheme is to give little or no discount on an item or service separately billed to Medicare, and give large discounts on items not separately billed to Medicare. This scheme results in Medicare paying a higher percentage for the separately billed item or service than it should.

For example, a lab offers a deep discount on lab work for which Medicare pays a predetermined fee (such as lab tests paid by Medicare to the facility as part of a bundled payment), if the facility refers to the lab its separately billed Medicare lab work, for which no discount is given. The lab calls this a "combination" discount, yet is a discount on some items and not on others. Another example is where ancillary or noncovered items are furnished free, if a provider pays full price for a separately billed item, such as where the purchase of incontinence supplies is accompanied by a "free" adult diaper. Medicare has not shared in these combination discounts.

H.R. 2389 Proposal. Section 202 would permit discounts on one item in a combination to be treated as discounts on another item in the combination. This sounds innocent, but it is not. Medicare would be a big loser. Discounting should be permissible for a supplier to offer a discount on a combination of items or services, so long as every item or service separately billed to Medicare or Medicaid receives no less of a discount than is applied to other items in the combination. If the items or services separately billed to Medicare or Medicaid receive less of a discount than other items in the combination, Medicare and Medicaid are not receiving their fair share of the discounts.

5. UNPRECEDENTED MECHANISM FOR ADVISORY OPINIONS ON INTENT-BASED STATUTES, INCLUDING THE ANTI-KICKBACK STATUTE.

Background: The Government already offers more advice on the anti-kickback statute than is provided regarding any other criminal provision in the United States Code.

Industry groups have been seeking advisory opinions under the anti-kickback statute for many years, with vigorous opposition by the Department of Justice (DOJ), and the HHS Office of Inspector General (OIG) under the last three administrations, as well as the National Association of Attorneys General. In 1987, Congress rejected calls to require advisory opinions under this statute. As a compromise, Congress required HHS, in consultation with the Attorney General, to issue "safe harbor" regulations describing conduct which would not be subject to criminal prosecution or exclusion. See Section 14 of Public Law 100-93.

To date, the OIG has issued 13 final anti-kickback "safe harbor" rules and solicited comment on 8 additional proposed safe harbor rules, for a total of 21 final and proposed safe harbors. Over 50 pages of explanatory material has been published in the Federal Register regarding these proposed and final rules. In addition, the OIG has issued six general "fraud alerts" describing activity which is suspect under the anti-kickback statute. Thus, the Government gives providers guidance on what is clearly permissible (safe harbors) under the anti-kickback statute and what we consider illegal (fraud alerts).

H.R. 2389 Proposal. HHS would be required to issue advisory opinions to the public on the Medicare/Medicaid anti-kickback statute (section 1128B(b) of the Social

Security Act), as well as all other criminal authorities, civil monetary penalty and exclusion authorities pertaining to Medicare and Medicaid. HHS would be required to respond to requests for advisory opinions within 30 days.

HHS would be authorized to charge requestors a user fee, but there is no provision for this fee to be credited to HHS. Fees would therefore be deposited in the Treasury as miscellaneous receipts.

Major problems with anti-kickback advisory opinions include:

- Advisory opinions on intent-based statutes (such as the anti-kickback statute) are impractical if not impossible. Because of the inherently subjective, factual nature of intent, it would be impossible for HHS to determine intent based solely upon a written submission from the requestor. Indeed, it does not make sense for a requestor to ask the Government to determine the requestor's own intent. Obviously, the requester already knows what their intent is.

- None of the 11 existing advisory opinion processes in the Federal Government provide advisory opinions regarding the issue of the requestor's intent. An advisory opinion process for an intent-based statute is without precedent in U.S. law.

- The advisory opinion process in H.R. 2389 would severely hamper the Government's ability to prosecute health care fraud. Even with appropriate written caveats, defense counsel will hold up a stack of advisory opinions before the jury and claim that the defendant read them and honestly believed (however irrationally) that he or she was not violating the law. The prosecution would have to disprove this defense beyond a reasonable doubt. This will seriously affect the likelihood of conviction of those offering kickbacks.

- Advisory opinions would likely require enormous resources and many full time equivalents (FTE) at HHS. The user fees in the bill would go to the Treasury, not to HHS. Even if they did go to HHS, appropriations committees tend to view them as offsets to appropriations. There are no estimates of number of likely requests, number of FTE required, etc. Also, HHS is permanently downsizing, even as it faces massive structural and program changes. The possible result of the bill is a diversion of hundreds of anti-fraud workers to handle the advisory opinions.

For the above reasons, DOJ, HHS/OIG and the National Association of Attorneys General strongly oppose advisory opinions under the anti-kickback statute, and all other intent-based statutes.

6. CREATION OF TRUST FUND MECHANISM WHICH DOES NOT BENEFIT LAW ENFORCEMENT.

Background: In our view, the most significant step Congress could undertake to reduce fraud and abuse would be to increase the resources devoted to investigating false claims, kickbacks and other serious misconduct. It is important to recognize that the law enforcement effort to control Medicare fraud is surprisingly small and diminishing. There is evidence of increasing Medicare fraud and abuse, and Medicare

expenditures continue to grow substantially. Yet, the staff of the HHS/OIG, the agency with primary enforcement authority over Medicare, has declined from 1,411 employees in 1991 to just over 900 today. (Note: 259 of the 1,411 positions were transferred to the Social Security Administration). Approximately half of these FTE are devoted to Medicare investigations, audits and program evaluations. As a result of downsizing, HHS/OIG has had to close 17 OIG investigative offices and we now lack an investigative presence in 24 States. The OIG has only about 140 investigators for all Medicare cases nationwide. By way of contrast, the State of New York gainfully employs about 300 persons to control Medicaid fraud in that State alone.

Ironically, the investigative activity of OIG pays for itself many times over. Over the last 5 years, every dollar devoted to OIG investigations of health care fraud and abuse has yielded an average return of over $7 to the Federal Treasury, Medicare trust funds, and State Medicaid programs. In addition, an increase in enforcement also generates increased deterrence, due to the increased chance of fraud being caught. For these reasons, many fraud control bills contain a proposal to recycle monies recovered from wrongdoers into increased law enforcement. The amount an agency gets should not be related to how much it generates, so that it could not be viewed as a "bounty." The Attorney General and the Secretary of HHS would decide on disbursements from the fund. We believe such proposals would strengthen our ability to protect Medicare from wrongdoers and at no cost to the taxpayers. The parties who actually perpetrate fraud would "foot the bill."

H.R. 2389 Proposal: Section 106 would create a funding mechanism using fines and penalties recovered by law enforcement agencies from serious wrongdoers. But none of the money would be used to help bring others to justice. Instead, all the funds would be used only by private contractors for "soft" claims review, such as, medical and utilization review, audits of cost reports, and provider education.

The above functions are indeed necessary, and they are now being conducted primarily by the Medicare carriers and intermediaries. Since the bill would prohibit carriers and intermediaries from performing these functions in the future, there appears to be no increase in these functions, but only a different funding mechanism.

These "soft" review and education functions are no substitute for investigation and prosecution of those who intend to defraud Medicare. The funding mechanism in H.R. 2389 will not result in any more Medicare convictions and sanctions.

In summary, H.R. 2389 would:

- relieve providers of the legal duty to use reasonable diligence to ensure that the claims they submit are true and accurate; this is the effect of increasing the Government's burden of proof in civil monetary penalty cases;

- substantially increase the Government's burden of proof in anti-kickback cases;

- create new exemptions to the anti-kickback statute which could readily be exploited by those who wish to pay rewards to physicians for referrals of patients;

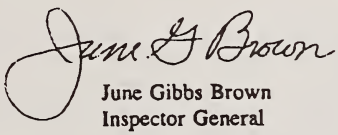
- o create an advisory opinion process on an intent-based criminal statute, a process without precedent in current law; since the fees for advisory opinions would not be available to HHS, our scarce law enforcement resources would be diverted into hiring advisory opinion writers; and

- o create a fund to use monies recovered from wrongdoers by law enforcement agencies, but the fund would not be available to assist the law enforcement efforts; all the monies would be used by private contractors only for "soft" payment review and education functions.

In our view, enactment of the bill with these provisions would cripple our ability to reduce fraud and abuse in the Medicare program and to bring wrongdoers to justice.

Thank you for your attention to our concerns.

Sincerely,



June Gibbs Brown
Inspector General

VOLUNTARY DISCLOSURE PROGRAM

Senator HARKIN. Do you have any other comments on this at all, Mr. Grob?

Mr. GROB. If you wish, I could just give a brief summary of the reasons or just, as you say——

Senator HARKIN. Sure. Could you do that very briefly?

Mr. GROB. I believe I could fairly quickly.

Senator HARKIN. OK.

Mr. GROB. We find some things good in the bill, the voluntary disclosure program, the establishment of minimum exclusion periods and higher penalty amounts.

The things we have trouble with is that it does raise the standard of proof for the kickback statute to the point that it would be extremely difficult, if not impossible, to prove fraudulent activity.

Under this proposal we would have to prove that the significant purpose of a payment is to induce referrals, which legally presents a much, much higher standard, and is much more difficult to prove.

The bill contains a broad exception to the kickback statute for certain managed care arrangements. In the case of an HMO, a kickback exclusion is perfectly legitimate, because if a single per capita payment is made, the incentives for referrals are lessened quite a bit.

But this extension is so vague and sweeping that it applies to risk sharing, disease management programs and any kind of capitation arrangement that we are afraid we would not be able to enforce the kickback statute in many, many cases.

There is an expansion to the discount exception to the kickback statute, which would have the effect of allowing providers and suppliers to offer discounts in their non-Medicare business and then

charge the full price for Medicare, so that, in essence, Medicare ends up paying for the discounts that are provided to others.

It requires us to issue advisory opinions on the kickback statute, and that would be all consuming for us and practically impossible since the kickback provisions require us to determine the intent that someone has in their actions.

And it is difficult for us to answer what someone else's intent is. They could probably figure it out for themselves, but basically this would consume our lawyers, and they would have very little opportunity for anything else.

There is a mechanism which we like, the idea of returning some of the fines and penalties to be used for law enforcement. But in this bill, the fines and penalties are not available for law enforcement.

They are to be provided to private contractors for doing different types of utilization reviews. We think it would be very important that some of the money from the fines and penalties be returned for law enforcement.

Right now, our resources have dwindled to the point that in 24 States, we do not even have investigative coverage at this stage. So getting some of those fines and penalties back to us, we think, would be very helpful, and other law enforcement agencies as well.

Senator HARKIN. Very good.

Mr. GROB. Thank you.

Senator HARKIN. Any last thing, Mr. Ratner?

Mr. RATNER. I would just add that on that last point, we think that it is important to fund a broad array of program safeguard activities, both the downstream activities of law enforcement and upstream activities that involve the preventive actions that contractors undertake.

And we would like to see funding mechanisms that would permit this over many years to be sustained and for CBO to score, but we also think that this means real savings that Medicare could yield from both the upstream and downstream activities.

Senator HARKIN. Well, I thank you both very much, both the GAO and the Inspector General's Office, for your diligence and your effort to look into these and for the fine reports that you have issued. We will follow up on them.

I thank you both again.

Health Care Financing Administration

STATEMENT OF BRUCE VLADECK, ADMINISTRATOR

Senator Harkin. Next we will call Mr. Bruce Vladeck, Administrator of the Health Care Financing Administration.

Mr. Vladeck, welcome. I have a draft copy of your statement. If that is your statement, I will have it put in the record in its entirety.

Mr. Vladeck. I believe it was unchanged from the draft, sir.

Senator Harkin. Well, whatever your final statement is, we will put it in the record.

Please proceed, Mr. Vladeck.

Mr. Vladeck. Thank you very much, Senator.

I appreciate the opportunity to be here today to discuss the way we monitor and process claims for durable medical equipment, prosthetics, orthotics, and medical supplies.

In the past several years, as I think the previous testimony suggested, we have been making significant progress in making Medicare more efficient, in making it serve beneficiaries better and making it less vulnerable to waste, fraud and abuse. I think we are to some extent beginning to turn the tide in some of these areas.

Of course we cannot do this alone, and we must rely on the support of many others. In particular, I would like to thank you, Senator, as well as other members of this subcommittee, for the assistance and often prodding and urging you have given us to help further our efforts.

Medical supplies constitute a small but significant portion of Medicare part B services. Medicare pays too much for many of these items, and they are vulnerable to abuse. To address many of the problems in this area requires changes in statute.

Your bill, S. 1193, the Medicare Waste and Abuse Reduction Act of 1995, provides a good example of the kinds of legislation that would help prevent further waste in this area.

For example, current law prevents Medicare from easily reflecting market forces in setting our payment rates for durable medical equipment and related items.

As the GAO report demonstrates, we are now paying prices for many of these items and services that are much higher than those available in the marketplace, but our statutorily established pricing structure keeps us from responding flexibly to the market and lowering what we pay.

Competitive bidding is a very promising way of establishing reasonable market prices for durable medical equipment and related items, particularly items that we buy in high volume.

In some instances, competitive bidding may not be appropriate for low volume items or in certain rural areas.

An alternative approach would be to adjust our prices through the process referred to as inherent reasonableness, in which we ex-

amine the prices and availability of services on the open market and set prices accordingly.

Under current law, the Secretary has inherent reasonableness authority for durable medical equipment and related items. However, the existing reasonableness authority, as we have discussed in the past, Senator, is time-consuming and bound by complexities.

Even on the most expeditious schedule, over a year is consumed because of the requirements for data gathering, industry consultations, proposed Federal Register notice with 60-day comment period, consideration of public comments and preparation of a final Federal Register notice.

For surgical dressings, even this remedy is not available. Under current law, we do not have the authority to adjust the statutory payment amounts for surgical dressings. Your bill, S. 1193, would permit competitive bidding for Medicare and simplify and speed up the inherent reasonableness process.

To decrease abuse, the GAO recommends that we require that bills submitted to fiscal intermediaries itemize supplies. We agree strongly with the need to prevent abusive claims for medical supplies, but we differ with the GAO on the appropriate strategy.

We believe the costs and additional burden of such a requirement on providers, and especially on our contractors, would outweigh the savings from the itemization.

Asking home health nurses and other medical professionals to write down and report on every bandage and gauze pad they use in order to catch a few abusive situations does not seem cost effective to us.

More importantly, as a matter of principle, we think the facilities or the providers should be responsible for the use of supplies within an overall payment, as has been the case with hospitals throughout the history of the Medicare Program.

We are now field testing prospective payment systems for both skilled nursing facilities and home health agencies in which the base payment to the provider would include the cost of all medically necessary supplies.

In the meantime, we think we can do better by carefully targeting our activities. We think we can identify significant abuse by suspending high-dollar and high-volume claims for review prior to payment.

During the quarter that ran from April through June of this calendar year, for example, 20 of our fiscal intermediaries denied $9.5 million in charges using these targeted approaches.

Over one-half of our fiscal intermediaries are targeting medical supplies for focused medical review, and we are reviewing whether those steps should be intensified.

We agree with the GAO recommendation that prepayment edits should be used to prevent inappropriate payments when coverage policy changes. In fact, carriers are required to revise their policies and edits to address national policy revisions.

When coverage for surgical dressings was expanded in March 1994, durable medical equipment regional carriers, the DMERC's, were instructed by us to implement certain item-specific screens in the absence of regional policies.

They were also given the flexibility to implement screens to address problems specific to their region. Those screens have been in use and have served to prevent abuses.

The DMERC's have now developed a detailed regional medical review policy in this area, which further strengthens our defense against inappropriate claims. This new policy of associated edits became effective yesterday.

The GAO report also recommends that HCFA establish procedures to prevent duplicate payments by contractors. Our major tool for preventing payment of duplicate part A and part B claims are edits in the common working file.

We are now looking at our procedures for use of the common working file to ensure we have used the capabilities of this system to the fullest. But that system, I must acknowledge, will never be nearly as effective or efficient as we need.

Beginning in 1997, the Medicare transaction system will give us a much-improved tool for eliminating duplicate claims. Since all claims will be processed in the same format by the same system, we will be able to monitor for duplicate claims much more easily and deny payments when duplicates are found.

The inspector general's report points to the difficult problem of appropriately tracking and paying for items of durable medical equipment for beneficiaries and skilled nursing facilities.

Under current law, each skilled nursing facility could decide whether certain items, including surgical dressings, are included in its routine costs or whether they will be billed separately under part B.

Part B benefits can be provided and billed by the facility or outside suppliers. This situation makes it difficult to track claims and ensure that they are appropriately paid, and statutory change is necessary to change this situation.

In conclusion, HCFA is strongly committed to combating waste, fraud, and abuse in the Medicare and Medicaid Programs. We are continuously looking for better approaches, and we appreciate the help that the GAO and OIG provide us, even if we do not always agree on the particular strategies they recommend.

PREPARED STATEMENT

We appreciate your help, Mr. Harkin, and that of the subcommittee in moving some of the legislative changes that we need to move forward, and we look forward to working with you on these and other measures to combat waste, fraud, and abuse.

Thank you.

Senator HARKIN. Mr. Vladeck, thank you very much.

[The statement follows:]

STATEMENT OF BRUCE C. VLADECK

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss issues relating to the way Medicare monitors and processes claims for durable medical equipment (DME), prosthetics, orthotics, and medical supplies. I will also respond to some of the findings and recommendations made by the General Accounting Office (GAO) and the Office of the Inspector General (OIG) in recent reports on payments made for medical supplies by the Health Care Financing Administration (HCFA).

HCFA has made it a priority to combat fraud, waste, and abuse throughout the Medicare and Medicaid programs. Medical supplies constitute a small but significant portion of Medicare Part B services and have been vulnerable to abuse. We have been taking a variety of steps to address abuse in this area, in the process responding to many of the concerns raised by this committee and the GAO.

I would like to explain a little about Medicare's coverage of medical supplies. Medical supplies are covered by Medicare in both inpatient (Part A) and outpatient (Part B) settings. Institutional providers, such as hospitals and nursing homes, submit both Part A (inpatient) and Part B (outpatient) claims to Medicare Fiscal Intermediaries for medical supplies. Physicians and suppliers submit claims for medical supplies to the Durable Medical Equipment Regional Carriers (DMERCs) under Part B.

Until 1993, claims from physicians and suppliers for medical supplies were processed by Part B carriers. Since October 1993, these claims have been monitored and paid by four specialized carriers called durable medical equipment regional carriers. The consolidation from 33 to 4 carriers has succeeded in making regional policies and coding guidelines more consistent. In addition, the DMERCs now closely monitor utilization trends and payment allowances for durable medical equipment, prosthetics, orthotics, and medical supplies.

CURRENT AND FUTURE SYSTEMS FOR MONITORING DME CLAIMS

The DMERCs utilize prepayment screens to detect inappropriate utilization. In addition, DMERCs use analyses of claims to detect trends in utilization and request additional information based on any aberrations.

When one of the DMERCs determines that a particular supplier has a pattern of submitting questionable claims, the DMERC will often request that the supplier submit additional documentation with the claim to justify the medical necessity of the item being ordered. In addition, each DMERC concentrates some of its post-payment medical review resources on specific suppliers who have been found to demonstrate unusual patterns of utilization. They subject particular items or services that have been found to be frequently abused to pre-payment and post-payment review. The DMERCs collect overpayments when appropriate.

To improve our information regarding utilization and payment trends, we established the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) to serve as a repository for all DMERC processed claims data. SADMERC data is then used to identify aberrant suppliers and high-dollar/high-volume claims for prepayment review. The SADMERC refers these aberrant suppliers to the DMERCs for further review.

HCFA uses conflict edits generated by the Common Working File (CWF) to alert contractors to the potential for a duplicate payment situation. For example, if a carrier or intermediary claim for outpatient supplies for a specific date is posted and Part A receives an inpatient claim for the same patient, over the same period of time, the CWF transmits an alert to the contractor. Questionable claims are then manually reviewed prior to payment.

In addition, every DMERC claim is checked against beneficiary history. If a duplicate is detected, the claim is not approved for payment. Also, each DMERC claim is checked to make sure that an item is not reimbursed if it is billed by more than one supplier.

Starting in 1997, Medicare will shift its claims processing to the Medicare Transaction System (MTS), achieving a complete modernization of its claim processing technology by 1999. Presently, Medicare processes nearly one billion claims a year using ten different software systems at 63 different sites. MTS will use a single software system, incorporating the latest computer technology, at a smaller number of sites.

The MTS will have a greater capacity to monitor and detect fraud and abuse by maintaining data on both Part A and B claims in a centralized, integrated system. The MTS will also incorporate additional edits and use upgraded computerized technology for screening the appropriateness of claims.

Through implementation of the MTS, new efficiencies will result in better monitoring and detection of abuse patterns and greater savings. For example, one beneficiary may have many different health care needs. This often means that four different providers prescribe varying treatments. At present, this beneficiary's claims might be processed by four different carriers, which cannot easily check other claims. Under the MTS, a single system will track all claims for each beneficiary and be able to identify easily any inappropriate claims.

MEDICARE PAYMENTS FOR DME SHOULD REFLECT MARKET PRICES

The GAO pointed out some areas that could result in savings to the Medicare program, but some of these recommendations would require changes in law. Current law prevents Medicare from reflecting easily market forces in setting its payment rates for DME and related items. As the GAO report demonstrates, Medicare is now paying prices for many of these items and services that are higher than those available in the marketplace, but Medicare's statutorily established pricing structure keeps us from responding flexibly to the market and lowering what we pay.

The Department of Veterans Affairs can achieve low prices on many items partly because it can purchase them through competitive bidding. Medicare does not have this ability.

Competitive bidding may not be appropriate for all items and in all areas of the country. An alternative approach is to adjust Medicare's prices through a process, referred to as inherent reasonableness, of examining the prices and availability of services on the open market and setting prices accordingly. The Secretary has inherent reasonableness authority under current law for durable medical equipment and related items.

As I have discussed in prior hearings, however, this authority is time-consuming and bound by complexities. Even on the most expeditious schedule, over a year is consumed because of the requirements for data gathering, industry consultations, proposed Federal Register Notice with 60 day comment period, consideration of public comments, and finalizing the Federal Register Notice.

For surgical dressings, even this remedy is not available. Under current law, Medicare does not have any authority to adjust payment amounts for surgical dressings.

Mr. Harkin's bill, S.1193, would simplify the inherent reasonableness process and permit the Secretary to delegate determinations to Medicare's contractors.

CLAIMS FOR MEDICAL SUPPLIES

The GAO recommends that HCFA require that bills submitted to fiscal intermediaries itemize supplies. While we agree that we need to prevent abusive claims for medical supplies, we differ on the appropriate strategy.

We believe that the cost and additional burden of such a requirement on providers and Medicare contractors would outweigh the value of the itemization. For medical supplies, codes would have to be developed for many of the items involved, a non-trivial task.

Even if we had codes, however, we would need to reflect on the point of asking home health nurses and other medical professionals to write down and report on every bandage and gauze pad they use in order to catch a few abusive situations. Most providers are honest and most individual items of medical supplies are minor in cost. Far better than requiring providers to make detailed reports on every item they use would be to make them responsible for use of supplies within an overall payment, as we now do for hospitals. We are now field-testing such prospective payment systems for skilled nursing facilities and home health agencies.

For the present, we think we can do better with less burden by carefully targeting our activities. Significant abuse can be identified by suspending high-dollar and high-volume claims for review prior to payment. During the April to June quarter of 1995, for example, a review of 20 of our fiscal intermediaries showed that 9.5 million dollars in charges were denied using these techniques. Over half of our fiscal intermediaries are targeting medical supplies for focused medical review, and we are reviewing whether further and more comprehensive steps are needed.

We agree with the GAO recommendation that prepayment edits should be used to prevent inappropriate payments when coverage policy changes; in fact, carriers are required to revise their policies and edits to address the national policy revision. When coverage for surgical dressing was expanded in March 1994, the DMERCs were instructed by HCFA to implement certain item-specific screens in the absence of a regional policy. The DMERCs were also given the flexibility to implement screens to address problems specific to their regions. These screens have been in use and have served to prevent abuses.

The DMERCs have developed a detailed regional medical review policy in this area, and this new policy and associated edits became effective yesterday, thus strengthening further our defenses against inappropriate claims.

The GAO report also recommends that HCFA establish procedures to prevent duplicate payments by contractors. As I mentioned earlier, Medicare pays for Part A and Part B claims differently. There are different codes, payment systems and contractors for both Part A and B. This creates difficulties, as GAO correctly assessed. Our major tool for preventing payment of duplicate Part A and Part B claims are edits in the Common Working File. We are now conducting a review of our procedures for use of the

Common Working File by contractors to insure we have used the capabilities of this system to the fullest.

Starting in 1997, the Medicare Transaction System will give us a much improved tool for eliminating duplicate claims. Since all claims will be processed in the same format by the same system, we will be able to monitor for duplicate claims much more easily and deny payment when they are found.

The Inspector General's report and testimony points to the difficult problem of appropriately tracking and paying for items of durable medical equipment for beneficiaries in skilled nursing facilities (SNFs). Under current law, each SNF can decide whether certain items, including surgical dressings, are included in its routine costs or whether they will be billed separately under Part B. Part B benefits can be provided and billed by the SNF or by outside suppliers. This situation makes it difficult to track claims and insure they are appropriately paid. Statutory changes would be necessary to change this situation.

CONCLUSION

HCFA is strongly committed to combatting waste, fraud and abuse in the Medicare and Medicaid programs. We are continuously looking for better approaches, and we appreciate the help that the GAO and the OIG provide us in focusing on these problems, even though we do not always agree on the strategies they recommend. We also appreciate the help of Mr. Harkin and the other members of the Subcommittee, and we look forward to working with you on measures to prevent and combat waste, fraud, and abuse

MEDICAL REVIEW SCREENS

Senator HARKIN. Again, you heard some of my earlier questions. I am going to get right into it here.

We had this expansion of benefits last year, and there were not adequate screens in place. Now, I read—you heard me read a portion of the letter signed by Tom Gustafson, Acting Director, Office of Legislative and Intergovernmental Affairs, May 13, 1994, that said by June 1, 1994, the DMERC's will implement medical review screens for selected items, et cetera. I read that earlier.

On that hearing on April 22 you said that the changes you were making would help you catch patterns of abusive billings, and I am going to read back your statement.

You said:

> We are now going to require our DME carriers to look at medical necessity on a systematic basis regardless of the duration of the prescription for the dressings, and so we believe we will be able to more effectively monitor that particular part of the pattern of abuse under the new rules than we were under the old rules.

But the investigation that GAO did, if I am not mistaken, found all kinds of things going on. You heard about the 240 yards of tape a day, the inspector general's finding of 12.5 miles of tape over 6 months.

How was this able to happen if in fact you assured me that you were going to have these screens in place?

Mr. VLADECK. Senator, the screens were in place.

They do not include the home health agency claims, which are submitted in an entirely different billing process through the intermediaries, nor do they include the skilled nursing facility claims, which are submitted to the intermediaries. This is a major

part of the problem and one that we probably were slower in identifying than we should have been. However, those screens are primarily used by the DMERC's on the part B claims that are submitted separately by suppliers.

For those, the review process is necessarily more targeted and more focused and retrospective than is the case for the claims that are submitted directly to the DMERC's. The DMERC's screens were put in place last spring.

We think they are partially responsible for the fact that the amount we paid for surgical dressings under part B in 1994 fell 22 percent below what we had spent on surgical dressings in 1993, notwithstanding the expansion in coverage.

Nonetheless, it took us longer to get the problem in the home health agencies under the first pieces of control, and we are not confident we have them entirely under control yet.

Senator HARKIN. Well, maybe I am a little confused here. Looking at this chart up here on the room care, they said they found $65 million of $98 million were questionable payments and would not have been paid if the new screens had been in place. The screens that you put in yesterday have been in place——

Mr. VLADECK. Yes, sir; although again, I believe, if I understand correctly the inspector general's testimony, that most of that $65 million in questionable payments involved supplies billed by home health agencies or skilled nursing facilities.

Senator HARKIN. But they were not part B.

Mr. VLADECK. That is correct.

Senator HARKIN. Well, I am told by my staff they are all part B.

Mr. VLADECK. But a large section were billed by the home health agencies and processed by the intermediaries.

Senator HARKIN. I do not care how they came. Let us back up. These are part B claims, are they not? And you said the screens were in place for part B, and it reduced the cost to part B over the last year and a half. But these are part B claims. And you are saying they are part B, but they came through some other——

Mr. VLADECK. I believe these are medical supply claims that are processed by home health intermediaries, as are all claims from home health agencies.

Senator HARKIN. Where is Mr. Ratner? Did he leave? I should have had him stay here. Well, let me read it here. This is the GAO report.

[Pause.]

Senator HARKIN. Well, it says right here, unless you are mistaken, Medicare part B allowed $65 million from June 1994 through February 1995 for 46 million wound care supplies that exceed the proposed DMERC guidelines. This represents 66 percent of $98 million in Medicare part B allowances.

Mr. VLADECK. Senator, it is one of the complex glitches in the system. The great majority of those claims were processed by the home health intermediaries. Under current law, the home health agencies are required to bill for medical supplies they provide to their patients through their own part A intermediaries even though medical supplies are a part B covered benefit.

Those claims are processed by the home health intermediaries, not by our medical equipment and supply carriers DMERC's.

And the screens used by the intermediaries, we have acknowledged, have not been as effective and have not been put in place in the same time cycle as the screens for the bills that were submitted directly to the durable medical equipment carriers.

Senator HARKIN. I guess what I am wondering is why did we expand all this service without having the screens in place in the first place?

Mr. VLADECK. Well, again, sir, I think we were not cognizant of the extent to which the proportion of all medical supplies billings had shifted from community-based billings that went to the DMERC's to the home health agencies that went to the intermediaries.

Again, we did have controls in place for the non-home-health-agency bills when the new policy went into effect. That policy has been subsequently significantly refined and expanded, but it and the related controls were not in place for the bills submitted by the home health agencies last spring.

Senator HARKIN. You said you had the detailed guidelines, though.

Mr. VLADECK. We had a number of specific screens and edits which we required the durable medical equipment carriers to implement in April of last year.

Senator HARKIN. Well, then, why were those not made part of the regulations? I mean, why did you not implement those?

Mr. VLADECK. We did implement them for the medical equipment carriers.

Senator HARKIN. Well, what went into place yesterday?

Mr. VLADECK. Expanded medical review policies for DMERC's and intermediaries, which go into substantially more detail and require still further documentation and questioning of surgical dressings.

But 70 percent of all part B claims that came into the system last spring were subject to automatic computer edits and computer screens that we put in place last April.

Senator HARKIN. Seventy percent of part B—say that again.

Mr. VLADECK. Seventy percent of the claims that came into the part B carriers DMERC's for medical/surgical dressings, beginning last April, were subject to special computerized edits and screens that required more intensive review of those claims.

Senator HARKIN. But those were all just part B.

Mr. VLADECK. Those were all claims submitted directly to the DMERC.

Senator HARKIN. And why was it only 70 percent? What happened to the other 30 percent?

Mr. VLADECK. We did not have automatic edits on those supplies; we had different kinds of statistical reviews.

Senator HARKIN. Well, why did you not have screens in place for part A? I am still coming back to this. I do not understand. We expand this coverage.

You tell me in your statement of last April that you are going to require DME carriers to look at medical necessity on a systematic basis to be able to more effectively monitor that particular part of the pattern of abuse under the new rules.

The letter I have from Mr. Gustafson says that by June 1, the DMERC's will implement medical review screens for selected items. What am I missing here?

Mr. VLADECK. What you are missing, Senator, is what we missed, which is the volume of claims for surgical dressings that do not come in through the DMERC's. As required by law, claims for supplies provided to home health agency recipients are sent to the home health agency intermediaries.

And we were not as quick in putting the new review policies into place for claims submitted by home health agencies to intermediaries.

Senator HARKIN. Mr. Reineke informs me that the detailed procedures that you put into place yesterday, that in fact you did not have these in place even before for the 70 percent.

Mr. VLADECK. That is correct. We had rather more simple and less sophisticated screens in place since last spring.

Senator HARKIN. So again, you are saying that is what allowed this to happen. Why did we not have those in effect on June 1, 1994?

Mr. VLADECK. Well, you cannot get a medical consensus on appropriate medical indications associated with a coverage policy until you have the policy.

So as soon as the draft policy circulated last spring changing the definitions of coverage, the process went into motion to develop detailed medical review guidelines or the actual clinical rules to determine when a particular service is considered to be appropriate.

Those medical review guidelines were circulated for public comment at the very beginning of this calendar year and have been in the process of revision and updating ever since. In the interim, we were using some other more simplified screens on the part B claims.

Senator HARKIN. We will review the record on that.

The GAO found that 89 percent of the paid claims for medical supplies should have been partially or totally denied; 61 percent of total payments should have been denied. They recommended that all claims be itemized, and you disagreed with that recommendation. Why?

Mr. VLADECK. As the GAO and the inspector general both found, I believe, the high proportion of what they identify as the questionable or abusive claims take place in a relatively limited number of states and involve a relatively limited number of providers.

We believe that it is much more cost effective in the short run to focus on detailed reviews of claims from those high-end claimers rather than requiring that level documentation for every single medical equipment claim.

In the long term, we believe we should not be paying separately for medical equipment and supplies. These items ought to be part of the routine cost payments to home health agencies or skilled nursing facilities. Over time, we beleive we should not pay separately for the provider-supplied supplies at all.

Senator HARKIN. That was the suggestion made by the inspector general right before you. I will look at that, but I am still concerned about having competitive bidding. I have long advocated that.

Mr. VLADECK. We are all in favor of it, Senator.

Senator HARKIN. Do you support——

Mr. VLADECK. Absolutely.

Senator HARKIN. But you said maybe some, maybe—you said maybe not for less utilized items or rural areas. Why could you not just set up, like we did in our proposed bill, regions, let the Secretary set up the regions, you have a list of all the items and put it out for competitive bids?

Mr. VLADECK. We would very much like to do that. The history of competitive bidding for some of these supplies in some of these communities is that there may well be instances in which you are only getting one bid. And the pricing may not be to the Government's advantage in those instances.

Senator HARKIN. But if you did it for a region, you are going to get more than one bid.

Mr. VLADECK. Well, perhaps, if you define the region broadly enough. In the past in other examples, there have been difficulties making sure that some of the smaller providers, some of the more outlying areas, received adequate services.

Senator HARKIN. If a supplier in Pennsylvania is supplying Atlantic, Iowa, then this stuff is moving across State lines and across the country anyway.

Mr. VLADECK. If we can do it all through competitive bidding, we would be perfectly happy. If there are parts of the country that do not get reasonable bids, then we need other methods. But the first attempt you make is competitive bidding.

Senator HARKIN. Well, I would like to look at that. But please do not tell me about less utilized. I was involved in competitive bidding several years ago in the WIC Program, the women, infant, and children's formula rebate program. And we got that through by 1990. We saved billions of dollars on it.

Do you know how many suppliers there are?

Mr. VLADECK. Four, I think.

Senator HARKIN. Five. So, I mean, I was told the same thing. We only have five. You are not going to get much of a break on this. Just since 1991, we have reduced the cost of formula by $4.1 billion.

Mr. VLADECK. We think we could obtain parallel results on medical equipment and supplies as well, and we would be very supportive of it.

Senator HARKIN. And look what the VA is doing. I mean, have you ever requested this from the—and I am not the authorizing committee.

I am sort of trying to point this out year after year. I am not on the authorizing committee. That is the Ways and Means Committee and the Finance Committee.

Has HCFA ever come out and said, "Please do this"?

Mr. VLADECK. Yes; on a number of occasions.

Senator HARKIN. You have asked them to do competitive bidding.

Mr. VLADECK. Yes.

Senator HARKIN. And they have turned a deaf ear.

Mr. VLADECK. No; they have explicitly rejected it. At one point in the 1980's, the authorizing committee forbade us from conducting demonstrations of competitive bidding.

We are about to begin a competitive bidding demonstration, because that provision has expired.

Senator HARKIN. Well, I want to make it very clear, and for the record, that I remember that instance in the 1980's. People have asked me, and I was asked that question this morning about why are we not going after this waste and abuse.

Well, the fact is there are very powerful forces out there making a lot of money on this. And the last thing they want is competitive bidding. They have a sweetheart deal going. And this is a lot of money.

People say, "Well, you can save a few million here or there."

Let me ask you, Mr. Vladeck: GAO has consistently told me over the last few years that they are estimating about 10 percent of HCFA's payments—and this is for DME, bandages, supplies, things like that—is going out for waste, fraud, and abuse.

Do you think that is too high an estimate?

Mr. VLADECK. In the areas of home care, durable medical equipment and supplies and some other services, our experience in south Florida over the last year, where we have had an intensified integrated pilot of our Operation Restore Trust, suggests that in those three areas at least, 10 percent may be a very conservative estimate.

For the bigger pieces of the program, such as inpatient hospital care and physician services, we suspect that the proportion is much lower. So it is hard to know how to average it over the whole program.

But in certain pockets of activity within the Medicare Program from the limited experience we now have from our concentrated efforts in some parts of the country, 10 percent may be a conservative estimate for some areas.

Senator HARKIN. Well, I am not going to give up on competitive bidding. Now, you say the provision in that law has expired. When did it expire?

Mr. VLADECK. The provision that forbade us——

Senator HARKIN. That prohibited you from doing demonstrations.

Mr. VLADECK. That provision has expired, I believe, in 1992. I hope that before calendar 1995 is out, we will begin competitive bidding in one region of the country on a demonstration basis.

Senator HARKIN. Well, I think we have already had demonstrations. The Veterans Administration. You do not get a much better demonstration than that.

Mr. VLADECK. Senator, the only authority we have to do competitive bidding at the moment is under our demonstration authority. We are supporting legislation to give us competitive bidding authority in general.

Senator HARKIN. Has the Secretary requested from the authorizing committees this year the ability or the authority to engage not in demonstration but to actually engage in competitive bidding? Has that letter—has that been transmitted, do you know?

Mr. VLADECK. I do not believe there has been a letter, sir, because of some of the other issues surrounding Medicare legislation this year, but we have been in conversation with staff of both the minority and majority side of the authorizing committees about such proposals.

Senator HARKIN. Mr. Reinecke just informed me that that was part of the President's health care bill last year, to include competitive bidding.

As you know, we have looked in the past at ambulance services and oxygen equipment. We have been through this before. We believe that there is billions in potential losses over the next 7 years due to just these two items, ambulance and oxygen.

You have been working on it. What is the update?

Mr. VLADECK. Let me talk about oxygen first, Senator. We expect to publish a proposed notice on inherent reasonableness on oxygen in October. This is pretty much on the schedule that I talked to you about last December.

That would still permit us, depending on the nature of the public comments and what we learned during that period to issue final guidelines by the end of the calendar year.

I must tell you, however, that within the last several weeks, I have had letters from a number of your colleagues accusing us of a rush to judgment in terms of the oxygen inherent reasonableness process.

Senator HARKIN. Look, I know they are out there. I have been approached. As much as I have been on this, I have been approached by representatives of the oxygen industry saying can we not do something else. Well, look, I understand that. They are making a killing. And I just hope you ignore those letters, if you get them. And under the Freedom of Information Act, I will ask you for them. I will get them myself.

Mr. VLADECK. We will not ignore them, and we will not ignore any information anyone gives us, Senator. We are required to take into account all comments we receive, and we will. The industry is providing some additional data, and we have told them that as soon as they get it to us, we will take it into account. But the process is proceeding.

Senator HARKIN. Well, I sure hope so.

Mr. VLADECK. I hope also before the end of the year that we will have new proposed regulations and regulations out on ambulance services. I cannot, at the moment, give you a more precise date than that.

Senator HARKIN. Mr. Vladeck, I just must be really honest with you. I tell you, I go out to Iowa and I meet with my constituents.

I talk about waste and abuse, and the question always comes, "Well, why? Why are you paying for miles of bandages? Why do you not just stop this nonsense?"

And I try to tell them that we have to do this, that and the other. I am telling you, it is the hardest question I have to answer: Why do you not just stop it?

Mr. VLADECK. Believe me, Senator, I can relate entirely to that.

Senator HARKIN. But you are in charge. I mean, someone has to be in charge of this. I hate to come down hard on you, but I just get frustrated that something cannot be done.

Now let me read you this: The Social Security Act Amendments of 1994 gave you new authority to target both abused medical supply and equipment items and abusive providers and require prior authorization by Medicare before payments would be made for either. I am sure you are aware of this.

This is 1994.

The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experiences, are frequently subject to unnecessary utilization through a carrier's entire service area or portion of such area. The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom the Secretary has found a substantial number of claims have been denied or the Secretary has identified a pattern of over-utilization from the business practice of the supplier.

Can you not utilize this authority to crack down on these?

Mr. VLADECK. We have begun to do so, sir. In the States in Operation Restore Trust, we are pilot testing a variety of different ways to identify just what those procedures are and just who those suppliers are.

And we are targeting for prepayment review the claims on medical equipment and supplies or other services from particular suppliers in Florida and in the next few months in four other States, as well.

Senator HARKIN. Well, I hope so. I just have to tell you, Mr. Vladeck, as much as I have been on this, you know I have been on it for a long time, you have been very kind and giving me information.

I just think we have to simplify this whole thing. We just have to get to competitive bidding on a regional basis and end all this nonsense and all these pages of rules and regulations and just stick it out there.

Mr. VLADECK. Nothing would please us more, sir.

Senator HARKIN. I am glad to hear you say that. Nothing would please me more either, and I think the taxpayers. I just look at what the Veterans Administration is doing.

I just think there are billions of dollars to be saved out there that we could do over the next 7 years. Well, I just hope that we can do that.

Is there a list of supplies and suppliers that we can get for the record on this prior authorization?

Mr. VLADECK. Senator, if I may, could we ask if we could submit some of that on a confidential basis to your staff and not for the record, because there are ongoing investigations in some of these?

Senator HARKIN. OK. Fine.

Mr. VLADECK. But we will be happy to provide such a list to your staff within the next week or 10 days in confidence.

Senator HARKIN. All right. We will honor that confidence. I do not want to disrupt any ongoing investigations. And I sure hope that some of these people get more than their wrists slapped on this stuff.

The inspector general's office had one here. This is what just drives me up a wall. Where is it? Right here, if I can find it. They had one in terms of fines and penalties. Here it is right here.

The owner of one company was convicted and sentenced for selling the names of Medicare beneficiaries, et cetera. The owner was sentenced to 26 months, 3 years probation, and repaid $75,000; $75,000, that is nonsense, and I know that is not your problem.

Here is another one. The owner of a second company, his company was fined $1,000. That does not do anything. I know that they—I see in November 1994 that the second company consented

to a civil judgment of $4.9 million. That is a civil judgment. I am talking about fines and penalties that they have to pay back to the Government.

I do not know. I mean, these are just slaps on the wrist. I mean, we need some more severe penalties than this to send a signal.

Oh, yes, the other one I wanted to—again, it is something I had not focused on before. In 23 percent of the nursing homes, the supplier determines the number of supplies to be delivered.

Mr. VLADECK. That is unacceptable, and it is contrary to current rules.

Senator HARKIN. Is that allowable under current Medicare rules?

Mr. VLADECK. No, sir.

Senator HARKIN. Then how come they are doing it?

Mr. VLADECK. I do now know, but we are examining this practice both in terms of work with authorizing committee staffs and in Operation Restore Trust investigations.

Senator HARKIN. So it is prohibited.

Mr. VLADECK. Well, a supplier may not order medical supplies for a skilled nursing facility resident. Only the nurse or a physician may order the supplies.

To the extent that nursing home managers/administrators have permitted the sales people from suppliers to take over those sorts of responsibilities, there is a serious question of violation of our rules.

So we may have a situation where the doctor or nurse did put in a general request for the bandages and so on, but that request was based upon information given to them by the supplier.

We have the same problem with all purchased things, that physicians or nurses or others get an enormous amount of sales advice. I am talking about prescription drugs, about generic drugs, about supplies and so forth.

And the law still gives physicians and nurses the principal responsibility for determining the medical needs of their patients. I do not know who else could do it.

Senator HARKIN. Well, again, if the inspector general's office is able to document this, then I would look from you a request in some kind of a change in statutory authority or whatever you need to stop that practice from happening, whatever that is.

Mr. VLADECK. Absolutely.

Senator HARKIN. Well, Mr. Vladeck, thank you again for being here. I just want for the record to recognize you have a tough job. Medicare last year was about $160 billion.

I figure that for the next several years, the average would be over $180 billion a year. So that is a lot to administer, a lot of different items. So I understand it is a tough job.

But we have to cut through this nonsense; 10 percent, maybe that is too much. I have said up to 10 percent, $18 billion a year, $126 billion over the 7-year period that could go to waste, fraud, and abuse.

I know that we cannot do all that. Is it one-half that much? Is it $60 billion? Is it $40 billion? I mean, I am just saying that the plan that we saw from the House is $2 billion.

Mr. VLADECK. Well, I think, sir, if you give us the tools, we will do better. There is no question. The issue of how CBO, and in fact

our actuaries, score averted expenditures is a fight that we are continuing to fight.

Senator HARKIN. I agree with you. This has been a fight we have been battling, too. We have the data. I think this subcommittee—I am not just saying myself—this subcommittee over the last several years has established the record.

The inspector general's office has established it. The GAO office has established. You have established it. And yet, they will not give the credit for the savings. Bizarre.

I cannot—you go explain that to the people out in Main Street. They cannot understand that. When you can save the money, but they will not give you the savings. Well, I get back the same, like a broken record. Let us get the competitive bidding. I think it would knock off a lot of this nonsense.

Mr. VLADECK. Absolutely.

Senator HARKIN. Thank you again, Mr. Vladeck. We will be in touch.

Mr. VLADECK. Thank you, sir.

Senator HARKIN. And if you can give me that information, we would appreciate it.

Mr. VLADECK. We shall.

Senator HARKIN. And we will keep it in confidence.

[The information follows:]

MEMORANDUM FROM TOM GUSTAFSON, ACTING DIRECTOR
OFFICE OF LEGISLATIVE AND INTERGOVERNMENTAL AFFAIRS

NOTE TO: Helen Smits, M.D.
SUBJECT: Surgical Dressing Medical Review Screens -- INFORMATION

May 12, 1994

The DMERCs have a multi-step plan to monitor utilization of surgical dressings. First, some edits, which were instituted earlier this year, remain in place at two of the DMERCs. All of the DMERCs are aggressively looking at the data and are already able to identify some suppliers that appear to be billing excessive amounts. These suppliers will be asked to provide documentation for medical review, on a postpayment basis, and if the services were not medically necessary, the DMERCs will seek recoupment. Other corrective action, such as referral to the DMERC fraud and abuse units, is also possible.

By June 1, 1994, the DMERCs will implement medical review screens for selected items that are high-cost or potentially subject to abuse. These screens will identify claims exceeding a specified number of services per month per beneficiary. There will be screens for both primary and secondary dressings. The DMERCs have identified those items they believe are most subject to overutilization, and believe that these screens will identify those items where excessive services (and, thus, dollars) are claimed.

On an ongoing basis, the DMERCs, with the assistance of the Statistical Analysis DMERC (SADMERC) (see attachment), will continue to monitor data on a postpayment basis so that they can develop regional medical review policies and screens for items which the data suggests need continued monitoring. This postpayment review of data may include identification of particular suppliers for either prepayment or postpayment review.

The Bureau of Policy Development is developing parameters to identify, for referral to the appropriate certification agency, those nursing facilities where the data suggests there may be quality of care issues.

Should you have any questions or require any further information, please let me know.

Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC)

Roles and Responsibilities

HCFA's contract for the SADMERC functions is with Palmetto Government Benefits Administrators. The SADMERC is charged with four primary responsibilities, including the coordination of coding activities, establishment of pricing files, postpayment medical review of national suppliers, and production of statistical reports.

As part of their data analyses activities, they will be receiving paid claims data from HCFA on a daily basis. With this data they will be producing a specified number of quarterly and annual reports on a periodic basis.

Examples of these reports will include:

- Item-Specific Reports, such as the top 100 DMEPOS HCPCS codes by allowed charges and item frequency, including the percentage change in utilization for these codes;

- Supplier-Specific Reports, such as the top 100 DMEPOS suppliers by allowed charges, and by allowed frequency of items; and

- Ordering Physician-Specific Reports, such as the top ordering physicians, and the top 50 physician/supplier relationship by billed dollars.

In addition, they will also act as a resource to the other DMERCs and HCFA, by producing up to three special request ("ad hoc") reports per month for each of the DMERCs and for HCFA. These report requests might include identifying specific suppliers who are billing an excessive number of surgical dressing items compared to the national average.

NONDEPARTMENTAL WITNESS

STATEMENT OF ROBERT CLOCK, CEO, CLOCK MEDICAL SUPPLY, INC., WINFIELD, KS

Senator HARKIN. Next, Mr. Robert Clock, CEO of Clock Medical Supply Co., of Winfield, KS, representing the Health Industry Distributors Association.

Mr. Clock, welcome, and your statement will be made a part of the record in its entirety.

Please proceed.

Mr. CLOCK. Thank you. Good morning.

Senator HARKIN. Good morning.

Mr. CLOCK. My name is Robert Clock. I am president and CEO of Clock Medical Supply, Winfield, KS.

Clock Medical Supply distributes medical/surgical supplies to roughly 40,000 elderly patients residing in long-term care centers. And of these patients, approximately 2,500 are served by Medicare part B and Medicaid Programs in Kansas, Oklahoma, and Missouri through our company.

My testimony today is on behalf of the Health Industry Distributors Association, or HIDA. Pursuant to a physician prescription, HIDA members provide durable medical equipment, prosthetics, orthotics and supplies, acronym DMEPOS, to Medicare beneficiaries being treated in their homes and in nursing facilities.

Mr. Chairman, I appreciate the opportunity to testify before your subcommittee today and commend you for holding this important hearing.

As someone with over 20 years of wound management experience, I can tell you first hand that the issues discussed today have a great impact on beneficiaries throughout the country.

At the onset, let me say that there are important elements to the OIG and the GAO reports with which we agree. In fact, many of the recommendations offered today are consistent with what the OIG and the GAO have recommended.

However, we have concerns about certain information omitted from these reports. Unfortunately, omissions lead to unfair and undeserved criticism of the Medicare Program and many DMEPOS suppliers who provide medically necessary services in a responsible way.

We applaud HCFA's establishment of the four DMERC's to process and oversee the DMEPOS benefits. This was an important step in eliminating fraud and abuse.

HIDA wants to continue to work with DMERC medical directors to ensure that beneficiaries continue to receive medically necessary wound care services.

This controlled DMERC environment is the best model for Medicare control of the program, particularly in comparison to nursing home cost reporting.

The problem that has occurred with the surgical dressing benefit was that the DMERC's failed to act in a timely manner to implement DMERC medical policy and definitive utilization and medical necessity parameters.

During the period before this policy was established, the DMERC's paid almost all submitted claims and thus created an environment conducive to fraud and abuse.

Patients should not be in jeopardy of losing a benefit due to the failure of government to timely implement utilization and medical necessity parameters.

The DMERC's have now developed a policy to clarify coverage of the wound care benefit. This policy was effective Sunday, October 1. HIDA urges this subcommittee to allow the new DMERC surgical dressing guidelines to be given a chance to take effect before reaching any definitive conclusions.

Importantly, the OIG concluded that three-quarters of excessive payments were made to 48 suppliers, only 7 percent of the sample. The surveys clearly omitted that the vast majority of suppliers are operating their businesses in a responsible manner.

The OIG surveys of nursing homes and beneficiaries appear critical of the valuable services provided by suppliers. For example, question No. 15 of the nursing home survey asked the following: Have supplier representatives ever helped you determine which patients in your facility qualify for Medicare reimbursement for wound care supplies?

What is omitted is the fact that if the supplier is billing Medicare for the supplies, the supplier has the responsibility to know Medicare's billing requirements.

The nursing facility frequently asks the supplier if a particular patient's condition meets the Medicare coverage requirements. This help is a positive service, not a negative one, and should be cited in the reports accordingly.

The OIG implies in the reports that the supplier access to patient charts is inappropriate. Medicare frequently reminds suppliers that they are ultimately responsible for ensuring that the suppliers' claims are accurate and medically necessary.

A responsible supplier would thus ask for verification that supplies billed to Medicare are indeed medically necessary and used by the patient through access to the nursing facility patient charts.

We would respectfully suggest that any medical information copied from a patient chart be documented and that the nursing center be the controller of access.

Mr. Chairman, HIDA is interested in working with you, your subcommittee, government agencies, nursing centers, beneficiaries and responsible parties to ensure that the surgical dressing benefit provides medically necessary care to beneficiaries without any fraudulent or abusive activities.

First, HIDA recommends that prescribing physician complete a certificate of medical necessity for supplies billed to part B only for those items found to be over-utilized and for those suppliers found to be abusive. HIDA has developed a model medical necessity form, included as attachment A.

Second, HIDA recommends that HCFA and the DMERC's establish a technical review committee whose primary responsibility

would be to review and analyze data resulting from the surgical dressings Medicare benefit.

The committee would suggest specific prepayment screens and refinements to the medical review policies based on post-payment audits and other relevant information, not to omit outcomes.

Third, HIDA supports efforts to consolidate billing for medical supplies into a nursing facility's Medicare part A cost report for billing which occurs during the Medicare covered nursing facility stay.

Mr. Chairman, finally, HIDA strongly opposes any changes to a supplier's ability to bill for Medicare part B medical supplies furnished to Medicare beneficiaries after the 100-day part A stay.

The Senate's Medicare Preservation Act should not allow only nursing home part B billing. A couple reasons for that, Senator. The majority of nursing centers currently have no part B or part A billing experience. The second most regulated U.S. industry does not need or want another bureaucratic layer.

We are not certain, but we believe, that the plan ignores retirement care facilities and nursing facilities and the beneficiaries therein.

PREPARED STATEMENT

Mr. Chairman, HIDA appreciates the opportunity to testify before your subcommittee today. And on behalf of the 2,500 Medicare part B patients that we serve, I will be glad to address any questions that you or your colleagues may have. Thank you.

[The statement follows:]

STATEMENT OF ROBERT CLOCK, ON BEHALF OF THE HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

EXECUTIVE SUMMARY

There are important elements in the draft reports on wound care supplies, entitled *"Questionable Medicare Payments for Wound Care Supplies,"* *"Marketing of Wound Care Supplies,"* and *"Wound Care Supplies: Operation Restore Trust Data,"* issued by the Office of the Inspector General (OIG) and the August 1995 General Accounting Office (GAO) report, entitled *"Excessive Payments for Medical Supplies Continue Despite Improvements"* with which we agree. In fact, many of our recommendations which we will offer today are consistent with what the OIG and GAO has recommended. However, we have concerns about certain misinformation cited in these reports. Unfortunately, this type of misinformation leads to unfair and undeserved criticism of the Medicare program and many DMEPOS suppliers who, pursuant to a physician prescription, provide medically necessary services to beneficiaries and nursing homes in a responsible manner.

Suppliers provide critical functions which hold down or eliminate costs the nursing facility would incur, including the following:

- *Billing/collection* activities
- *EDI/Bar Code Technology*
- *Delivery/Transportation/Inventory Management*
- *Value-Added Services*

The findings in the reports, however, were misleading and not representative of the current marketplace. The following are highlights of the problems we discovered after reviewing the OIG reports:

- The OIG unfairly applied DMERC draft guidelines which will not be in effect until October 1, 1995 to identify questionable supplier billing practices.
- The OIG survey presented misleading and one-sided questions to nursing homes and beneficiaries.
- The OIG should give greater emphasis to its finding that the problems are limited to a small minority of suppliers and nursing facilities.
- The OIG incorrectly implies that legitimate market-driven supplier services are inappropriate.
- The OIG should survey suppliers to obtain a fair depiction of the marketplace before issuing the final reports.

The Durable Medical Equipment Regional Carriers (DMERCs) delay in developing surgical dressings medical policies with appropriate utilization and medical necessity parameters was the primary factor in creating an environment ripe for potentially abusive activities.

As we stand today, the DMERCs have finally developed a policy to clarify the coverage of the wound care benefit. This policy is expected to be effective October 1, 1995. HIDA urges this Subcommittee to allow the new DMERC surgical dressing guidelines to be given a chance to take effect before reaching any definitive conclusions.

HIDA Recommendations

HIDA has long advocated that a prescribing physician fill in a Certificate of Medical Necessity (CMN) for medical supplies billed to Part B for nursing home residents only for those items found to be overutilized and those suppliers found to be abusive. Ironically, the DMERCs have not required a medical necessity form for surgical dressings despite the government's perception that surgical dressings is an "overutilized" Medicare benefit.

HIDA is eager to work with the DMERCs and HCFA to track and analyze claims processing utilization data in order to ensure the appropriate administration and interpretation of the DMERCs surgical dressings medical review policies (as well as all other medical polices).

HIDA supports efforts to consolidate all billing for medical supplies into a nursing facility's Medicare Part A cost report for billing which occurs during the Medicare covered nursing facility stay. HIDA strongly opposes any changes to a supplier's ability to bill Part B for medical supplies furnished to Medicare beneficiaries after the first 100-day Part A stay. Therefore, after the Medicare covered Part A stay, nursing facilities may elect to permit independent suppliers to bill Medicare Part B on behalf of eligible beneficiaries that no longer qualify for the Part A skilled nursing facility benefit.

I. INTRODUCTION

My name is Robert Clock, President and Chief Executive Officer of Clock Medical Supply in Winfield , KS. Clock Medical Supply distributes medical-surgical supplies to roughly 40,000 elderly patients residing in long term care facilities. Of these 40,000 patients, close to 2,500 are served by the Medicare Part B and Medicaid programs in Kansas, Oklahoma, and Missouri. In addition, Clock Medical Supply manufactures "restraint alternative" products designed to help prevent the elderly from falling in nursing homes and hospitals, and designs and distributes bar code scanning technology for the long term care industry.

My testimony today is on behalf of the Health Industry Distributors Association (HIDA). I serve as Region Four Director on HIDA's Long Term Care Market Group. HIDA is the national trade association of home care companies and health and medical product distribution firms. Created in 1902, HIDA now represents over 900 home care companies and wholesale and retail medical product distributors with nearly 2000 locations. Pursuant to a physician prescription, HIDA members provide durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) services to Medicare beneficiaries who are being treated in their homes and to beneficiaries residing in nursing homes.

Mr. Chairman, I appreciate the opportunity to testify before your Subcommittee today and commend you for holding this important hearing. As someone with over 20 years of wound management experience, I can tell you first hand that the issues discussed today have a great impact on beneficiaries throughout the country. I have reviewed the draft reports on wound care supplies, entitled *"Questionable Medicare Payments for Wound Care Supplies,"* *"Marketing of Wound Care Supplies,"* and *"Wound Care Supplies: Operation Restore Trust Data,"* issued by the Office of the Inspector General (OIG) and the August 1995 General Accounting Office (GAO) report, entitled *"Excessive Payments for Medical Supplies Continue Despite Improvements."*

At the onset, let me say that there are important elements in these reports with which we agree. In fact, many of our recommendations which we will offer today are consistent with what the OIG and GAO has recommended. However, we have concerns about certain misinformation cited in these reports. Unfortunately, this type of misinformation, which I will address in detail below, leads to unfair and undeserved criticism of the Medicare program and many DMEPOS suppliers who, pursuant to a physician prescription, provide medically necessary services to beneficiaries and nursing homes in a responsible manner.

II. HIDA'S RESPONSE TO REPORTS

- **THE DURABLE MEDICAL EQUIPMENT REGIONAL CARRIERS (DMERCS) DELAY IN DEVELOPING SURGICAL DRESSINGS MEDICAL POLICIES WITH APPROPRIATE UTILIZATION AND MEDICAL NECESSITY PARAMETERS WAS THE PRIMARY FACTOR IN CREATING AN ENVIRONMENT RIPE FOR POTENTIALLY ABUSIVE ACTIVITIES.**

The establishment of the four regional carriers, otherwise known as the DMERCs, by the Health Care Financing Administration (HCFA) to process and oversee durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) was an important step taken to help eliminate potential fraud and abuse. The new DMERC process is critical to the successful administration of

the Medicare DMEPOS benefit, and it is easy to lose sight of the fact that the DMERCs have been fully in place only since October 1, 1993. With full time Medical Directors developing very strict physician practice guidelines defining medical necessity for medical supplies (including the development and publication of specific limits on how many units of medical supply a particular Medicare beneficiary can receive), inappropriate over-utilization has and will be curbed. This controlled DMERC environment is the best model for Medicare control of the program, particularly in comparison to nursing home cost reports.

The problem that has occurred with the surgical dressings benefit was that the DMERCs failed to act in a timely manner to implement DMERC medical policies with definitive utilization and medical necessity parameters. The lack of these definitive guidelines was the prime factor causing abusive billing practices. As stated by the GAO on page 7 of their report, "for Medicare part B claims, the regional carriers have not adopted important fraud and abuse controls for many surgical dressing items. Specifically, the 29 surgical dressings covered by the expanded Medicare surgical dressing benefit have no formal medical policies specifying the conditions under which payment is to be made. Without these policies, regional carriers cannot implement systematic controls to identify questionable claims for review."

HIDA has long advocated the development of clinically sound surgical dressings medical policies. In fact, the OIG acknowledges on page 3 of their "*Questionable Medicare Payments For Wound Care Supplies*" that HIDA helped develop "consensus recommendations for improving the Medicare wound policy." HIDA developed these recommendations in order to ensure that potential abuse in the wound care benefit would be eliminated.

As we stand today, the DMERCs have finally developed a policy to clarify the coverage of the wound care benefit. This policy is expected to be effective October 1, 1995. HIDA urges this Subcommittee to allow the new DMERC surgical dressing guidelines to be given a chance to take effect before reaching any definitive conclusions. The product utilization guidelines combined with the billing modifiers, which identify the number of wounds on which a particular product is being used, should create future data which can be meaningfully analyzed. The OIG and GAO reports do not provide meaningful analysis because they were written prior to the development of a DMERC surgical dressings medical policy. As a result, patients should not be in jeopardy of losing a benefit due to the failure of the government to implement timely utilization and medical necessary parameters .

- THE FINDINGS IN THE REPORTS WERE MISLEADING AND NOT REPRESENTATIVE OF THE CURRENT MARKETPLACE

As I stated earlier, much information regarding the Medicare wound care benefit has been misrepresented to the public. The OIG reports, which were based on an OIG random national sample of roughly 400 nursing facilities and 469 beneficiaries as well as the OIG's inspections conducted as part of the Operation Restore Trust program, focus on the role of the supplier and thus it is important that we address the misrepresentations in these OIG reports in detail.

The following are highlights of the problems we discovered after reviewing the OIG reports:

- The OIG unfairly applied DMERC draft guidelines which will not be in effect until October 1, 1995 to identify questionable supplier billing practices.
- The OIG survey presented misleading and one-sided questions to nursing homes and beneficiaries.
- The OIG should give greater emphasis to its finding that the problems are limited to a small minority of suppliers and nursing facilities.
- The OIG incorrectly implies that legitimate market-driven supplier services are inappropriate.
- The OIG should survey suppliers to obtain a fair depiction of the marketplace before issuing the final reports.

Survey Process and Questions
HIDA is disappointed in the manner in which the OIG reports were developed and presented. The OIG wound care surveys which were mailed to nursing facilities and beneficiaries were one sided and misleading. Many of the questions directed at the nursing homes and the beneficiaries are phrased "has a supplier [or supplier representative] ever" or "have you ever." These questions are leading and ambiguous and if answered "yes," would result in an unfavorable portrait of the supplier even though the practice may have occurred once in the course of ten years.

Despite these misleading and one-sided questions, the OIG still found that the problems identified were limited to a very few suppliers, concentrated in a few states, and involved a limited number of nursing facilities. The OIG concluded that almost two-thirds of "excessive" wound care payments were found in eight states and that three-quarters of "excessive" payments were made to 48 suppliers, 7 percent of the sample. The surveys clearly reflect that the vast majority of suppliers are operating their businesses in a responsible manner.

Supplier Services Are Not Accurately Represented
The OIG does not cite the multitude of services which are provided by suppliers of DMEPOS items. Suppliers provide critical functions which hold down or eliminate costs the nursing facility would incur, including the following:

- *Billing/collection* activities required to generate patient specific product utilization information for payment of a product from payors for Medicare Part A, Part B and private
- *EDI/Bar Code Technology* to support order processing, product handling, packaging, billing and collection, and labor efficiency through time and motion study
- *Delivery/Transportation/Inventory Management* activities related to the movement of a product to the facility, within a facility (bar code, inventory management, storage) and activities required to send and receive product order information for the facility and for individual residents
- *Value-Added Services* including providing classes to nurses and clinicians for CEU credits on product availability and appropriateness for clinical objectives

These services are essential benefits that customers receive, and nursing facilities expect to receive, from suppliers in the marketplace and should be recognized and acknowledged by the OIG.

Not only does the OIG fail to acknowledge the important services provided by suppliers in the marketplace, they present surveys to nursing homes and beneficiaries that appear critical of valuable services provided by suppliers in the normal course of business. For example, question #15 of the nursing home survey asks the following: "*Have supplier representatives ever helped you determine which patients in your facility qualify for Medicare reimbursement of wound care supplies?*" Roughly 32 percent of nursing facilities responded "yes". What is not stated is the fact that if the supplier is billing Medicare for the supplies, the supplier has the responsibility to know Medicare's billing requirements. The nursing facility frequently asks the supplier if a particular patient's condition meets the Medicare coverage requirements. In this instance the supplier has helped the nursing facility determine if the patient qualifies for Medicare reimbursement. This help is a positive service, not a negative one, and should be cited in the reports accordingly.

Another example occurs when the OIG implies in the report(s) that supplier access to patient charts is inappropriate. Page 7 of the "*Marketing of Wound Care Supplies*" report states the following:

> "Wound care suppliers have requested to review medical records in 17 percent of nursing homes. These homes report that the reason suppliers give for review records is to determine the eligibility of patients, view the physician orders, record treatment progression, and to gather supporting documentation for billing purposes."

Medicare frequently reminds suppliers that they are ultimately responsible for ensuring that the supplier's claims are accurate and medically necessary. A responsible supplier would thus ask for verification that supplies billed to Medicare are indeed medically necessary and used by the patient, through access to nursing facility patient charts. It should also be noted that the new DMERC surgical dressing medical policy will require suppliers "to have a mechanism for determining the quantity of dressings that the patient is actually using and to adjust their provision of dressings accordingly."

OIG Bases Study On DMERC Draft Guidelines Which Are Not In Effect
What is perplexing is the fact the OIG in its *Wound Care Supplies: Operation Restore Trust* and *Questionable Medical Payments for Wound Care Supplies* reports "applied the proposed DMERC draft guidelines to these claims [claims analyzed for purposes of the reports] to identify questionable billing practices." The OIG is thus developing conclusions on what products "exceeded utilization guidelines" based on a policy that wasn't in effect during the time period studied (June 1994 through February 1995). Further, we question the OIG's assumption that one type of wound cover equals one wound site. A patient with multiple wounds could, and many times does, use the same type of wound cover for treating more than one wound. This assumption by the OIG led to an overstatement of how many wound care products were "unnecessary" since it didn't account for the fact the product could be used for more than one wound.

As you can see, the OIG "findings" are flawed thereby misrepresenting the role of the supplier and the fraud and abuse associated with the supplier industry.

III. HIDA RECOMMENDATIONS

Mr. Chairman, HIDA is interested in working with your Subcommittee, the DMERCs, HCFA, the OIG, GAO, nursing homes, beneficiaries and others to ensure that the surgical dressings benefit provides medically necessary care to beneficiaries without any fraudulent or abusive practices. This being the case, HIDA offers the following recommendations, many of which were cited by the GAO and OIG.

A. CMN's For Abusive Suppliers And Overutilized Items
First, we agree with the OIG's recommendation to HCFA, cited on page 13 of its "*Questionable Medicare Payments For Wound Care Supplies*" report that they "target their limited program integrity resources to those areas identified as most vulnerable to abuse." This is precisely why HIDA has long advocated that a prescribing physician fill in a Certificate of Medical Necessity (CMN) for medical supplies billed to Part B for nursing home residents only for those items found to be overutilized and those suppliers found to be abusive. HIDA has developed a medical necessity form, which we have included as Attachment A, to be used in such instances. It is imperative, however, that HCFA and the DMERCs establish a fair process, with appropriate procedural and substantive due process considerations in place, to ensure that those items deemed to be overutilized and those suppliers deemed to be abusive are determined in a fair manner

Abusive suppliers would be those who are placed on a list by the Secretary of Health and Human Services ("Secretary") in accordance with Section 1834(a)(15)(B)(i) and (ii) of the Social Security Act (amended by the Social Security Act Amendments of 1994). This section of the law states that the "Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom (i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1862(a)(1) ["items and services...are not reasonable and necessary for the diagnosis or treatment of illness or injury"]; or (ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier." Once again, suppliers must be afforded appropriate due process before being placed on such a list.

Overutilized items would be those placed on a list by the Secretary in accordance with Section 1834(a)(15)(A) of the Social Security Act. This section of the law states that "the Secretary may

develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary over-utilization throughout a carrier's entire service area or a portion of such area." If, for example, it is deemed that surgical dressings have been overutilized (based on appropriate due process considerations), then a medical necessity form should be required. Ironically, the DMERCs have not required a medical necessity form for surgical dressings despite the government's perception that surgical dressings is an "overutilized" Medicare benefit.

B. Technical Review Committee To Review Data

Second, HIDA is in complete agreement with the GAO when it states the following on page 12 of its report:

> "HCFA's consolidation of DME and medical supply claims processing at four regional carriers provides comprehensive national data - that were not available previously - on utilization and payments. These data will allow HCFA to identify, on a nationwide basis, DME and medical supplies that may be subject to overutilization and inappropriate billing. In 1993, HCFA also developed a programwide emphasis on data analysis. Calling its approach focused medical review, HCFA required contractors to begin identifying general spending patterns and trends that would allow them to identify potential problems....Armed with its new information from DMERCs and focused medical review program reports, HCFA is now much better positioned than in past years to provide HHS, the Office of Management and Budget, and the Congress with concrete information on contractor activities that save program dollars. "

We also applaud the OIG for its recommendation, on page 13 of *the "Questionable Medicare Payments For Wound Care Supplies"* report, that the DMERCs "edit screens...to track such wound care products as tape and hydrogel."

However, the DMERCs and HCFA can and should do more in this area. As we have stated on numerous occasions, HIDA is eager to work with the DMERCs and HCFA to track and analyze claims processing utilization data in order to ensure the appropriate administration and interpretation of the DMERCs surgical dressings medical review policies (as well as all other medical polices). This could be accomplished if the *DMERCs and/or HCFA established a technical review committee whose primary responsibility would be to review and analyze data resulting from the surgical dressings Medicare benefit.* The committee should consist of a wide range of representatives of organizations and patients, including suppliers, clinicians, claims processors, and patients/consumers. The committee would suggest specific prepayment screens and refinements to the medical review policies based on post payment audits and other relevant information. The committee could generate regular reports which would be the basis for positive changes to the surgical dressings policy.

For example, it would be particularly helpful to analyze the number of exceptions to the utilization parameters. If 80 percent of claims require additional documentation in order to appropriately exceed the utilization parameters set forth in a particular provision of the policy, it would then be legitimate to question whether that parameter is appropriate.

C. Consolidated Billing Proposal

Third, HIDA supports efforts to consolidate all billing for medical supplies into a nursing facility's Medicare Part A cost report for billing which occurs during the Medicare covered nursing facility stay. Therefore, only the nursing facility could bill for these services and supplies during the Medicare covered stay through its Part A cost report. To avoid any disruption of medically necessary supplies for the beneficiary, certain technical changes to Part A rules also need to be made. All enteral and parenteral nutrition products should be recognized as part of a nursing facility's ancillary costs, not routine costs.

HIDA strongly opposes any changes to a supplier's ability to bill Part B for medical supplies furnished to Medicare beneficiaries after the first 100-day Part A stay. Therefore, after the Medicare covered Part A stay, nursing facilities may elect to permit independent suppliers to bill Medicare Part B on behalf of eligible beneficiaries that no longer qualify for the Part A skilled nursing facility benefit. The Senate Finance Committee's Medicare proposal to limit the supplier's ability to bill Part B in these circumstances may compromise the nursing facility's ability to

provide high quality medically necessary wound care services to nursing facility residents. Nursing facilities contract with suppliers to provide Part B billing services because suppliers perform these functions far more efficiently than nursing facilities.

Importantly, the rationale for requiring that nursing homes bill for medical supplies in the nursing facility's Medicare Part A cost report is that it would eliminate the opportunity to simultaneously bill Medicare Part B for the same supplies. This rationale simply does not exist for residents receiving medically necessary wound care once the Part A stay has ended. HIDA's consolidated billing position paper is included as Attachment B.

IV. CONCLUSION

Mr. Chairman, HIDA appreciates the opportunity to testify before your Subcommittee today. I will be glad to address any questions you or your colleagues might have.

Attachment A

VOLUNTARY MEDICAL NECESSITY FORM: SURGICAL DRESSINGS

Completion Instructions: Supplier completes Section A; Health Care Professional completes Sections B and C; Physician completes Section D.

Section A: Patient Information

☐ Initial Certification ☐ Recertification ☐ Modification

Patient Name _____

Medicare Part B# _____ Date of Birth _____ Male ☐ Female ☐

Patient Address _____

WCC/Facility _____ Telephone _____

Co-Insurance _____ Policy # _____ Telephone _____

Section B: Clinical Information

Diagnosis _____ (ICD-9) _____ - _____ (ICD-9) _____

Diagnosis Affecting Healing Outcome	Additional Information (e.g., activity level, condition of surrounding skin, drainage, immobility, incontinence, mental status, nutritional status, support surface)
☐ Amputation ( )	
☐ Burn ( )	
☐ Dermtologic Lesion (709.9)	
☐ Open wound - Surgical Incision (879.8)	
☐ Pressure Ulcer (707.0)	
☐ Skin Graft/Flap (86.69)	
☐ Vascular Ulcer (707.1)	
☐ Other: _____ ( )	

Wound	Location	Type of Wound	Most Recent Procedure Date	L x W	Depth (Cm)	Tunneling	Infected	Procedure Code _____(if any) Debridement Type (if any)
1				x		Y or N	Y or N	☐Chemical ☐Mechanical ☐Surgical/Laser ☐Autolytical
2				x		Y or N	Y or N	☐Chemical ☐Mechanical ☐Surgical/Laser ☐Autolytical
3				x		Y or N	Y or N	☐Chemical ☐Mechanical ☐Surgical/Laser ☐Autolytical

Section C: Ordering Information

Wound: Circle 1 2 3 or All	HCPCS	Description of Dressings	Primary	Secondary	Quantity	Frequency	Quantity/Change (N/A for A4454)	X Time Period	Total Quantity
1 2 3 All			☐	☐					
1 2 3 All			☐	☐					
1 2 3 All			☐	☐					
1 2 3 All			☐	☐					
1 2 3 All			☐	☐					
1 2 3 All			☐	☐					
1 2 3 All			☐	☐					

Procedure(s) Performed by _____ UPIN _____ Telephone _____

30-Day Certification Period _____ To _____

Section D: Physician's Certification

Medicare Part B Carriers Manual, Coverage And Limitations, Section 2079: *Surgical Dressings Limited To Primary And Secondary Dressings, Required For The Treatment Of A Wound Caused By, Or Treated By, A Surgical Procedure That Has Been Performed By A Physician Or Other Health Care Professional To The Extent Permissible Under State Law. Surgical Dressings Required After Debridement Of A Wound Are Also Covered, Irrespective Of The Type Of Debridement, As Long As The Debridement Was Required And Was Performed By A Health Care Professional Who Was Acting Within The Scope Of His Or Her Legal Authority When Performing This Function.*

PROGNOSIS OF PATIENT: ☐ Good ☐ Fair ☐ Poor

PROGNOSIS OF WOUND: ☐ Wound Healing Expected ☐ Wound Stabilization Expected and/or Avoid Further Deterioration

I certify the medical necessity of these items for this patient. Section B of this form has been completed or reviewed by me. The foregoing information is true, accurate and complete.

Print Physician's Name _____ Physician's UPIN _____

Address _____ Telephone _____

Signature _____ Date _____

Attachment B

CONSOLIDATED BILLING POSITION PAPER

Position

HIDA supports AHCA's effort to consolidate all billing for medical supplies into a nursing facility's Medicare Part A cost report for billing which occurs during the Medicare covered nursing facility stay. Therefore, only the nursing facility could bill for these services and supplies during the Medicare covered stay through its Part A cost report. To avoid any disruption of medically necessary supplies for the beneficiary, certain technical changes to Part A rules also need to be made. All enteral and parenteral nutrition products should be recognized as ancillary, not routine costs. After the Medicare covered Part A stay, nursing facilities may elect to permit independent suppliers to bill Medicare Part B on behalf of eligible beneficiaries that no longer qualify for the Part A SNF benefit.

Background

The Medicare Part A program provides coverage for extended care services to residents of skilled nursing facilities of up to 100 days per benefit period. The Social Security Act specifies the covered services provided to a resident during a nursing facility stay, including medical supplies, enteral nutrition, urological supplies, and surgical dressings.

Part A Billing:
At the discretion of the nursing facility administrator, medical supplies may be billed either under Part A or Part B. If the nursing facility administrator decides to directly provide these services and supplies, then the cost is reported to Medicare Part A as part of the nursing facility's cost report as either an "ancillary" cost (e.g., medical supplies) or as a "routine" cost (e.g., enteral nutrition). The cost reports are submitted to Part A intermediaries which reimburse the nursing facility. The Medicare Part A intermediary imposes no standard coverage requirements or utilization controls on the beneficiary's use of medical supplies; instead the nursing facility's medical director has the discretion to determine appropriate coverage and utilization.

Part B Billing:
Alternatively, the nursing facility administrator may choose to have eligible residents receive certain medical supplies through the Medicare Part B program. If so, the nursing facility administrator has three options:

1. the nursing facility can obtain a supplier number and bill Medicare for the medical supplies under Part B;
2. the nursing facility can set up a separate corporation owned or controlled by the nursing facility and that corporation can obtain a supplier number and bill for the medical supplies under Part B;
3. the nursing facility administrator can request that an independent supplier or suppliers bill for the medical supplies under Part B.

If the nursing facility administrator chooses to have the services billed to Medicare Part B, then the supplier (which can be either the nursing home or an independent supplier) must meet specific requirements, must provide the supplies pursuant to a physician's written prescription, and must bill one of four Durable Medical Equipment Regional Carriers (DMERCs). The DMERCs impose specific standardized coverage requirements and utilization controls designed to curb inappropriate utilization. Additionally, beneficiaries are required to pay the 20 percent co-payment for all Part B services to further curb inappropriate utilization.

Functions Performed by Medical Product Suppliers

The decision of the nursing facility administrator to not bill Part B and thereby utilize a supplier is based in part on the benefit of functions performed by medical products suppliers that support the nursing home. These functions are often more efficiently provided by a supplier that is totally dedicated to these functions and hold down or eliminate costs the nursing facility would incur. The nursing facility may not be large enough or have the managerial time or capability to perform these functions directly or efficiently.

Billing/Collection: Activities required to generate patient specific product utilization information for payment of a product from payors for Medicare Part A, Part B and private. This includes the assumption of financial risk associated with future payment.

EDI/Bar Code Technology: Inventory management systems to support order processing, product handling, packaging, billing and collection, and labor efficiency through time and motion study.
Delivery/Transportation/ Inventory Management: Activities related to the movement of a product to the facility, within a facility (bar code, inventory management, storage) and activities required to send and receive product order information for the facility and for individual residents.
Value-Added Services: Variety of services that go beyond the basic distributor function. Value-added services, in general, help reduce costs and improve productivity throughout the supply chain.

- Education and CEU - provide classes to nurses and clinicians for CEU credits on product availability and appropriateness for clinical objective.
- Clinical support *e.g.*, nutritional assessment, ET for wound care protocols, RT for inhalation monitoring.
- Outcomes support. Match appropriate product to achieve efficacious clinical outcome.
- Satisfying demand by supplying goods and services at the right place, quantity, quality, and price for each bed.

Part B Recommendations

To further improve the Part B process, HIDA recommends standards specifically for suppliers billing Part B for medical supplies used by residents of nursing facilities. In addition, HIDA has long advocated that a prescribing physician fill in a Certificate of Medical Necessity (CMN) for medical supplies billed to Part B for nursing home residents for those items found to be overutilized and those suppliers found to be abusive. It is imperative that HCFA and the DMERCs establish a fair process, with appropriate procedural and substantive due process considerations in place, to ensure that those items deemed to be overutilized and those suppliers deemed to be abusive are determined in a fair manner.

COMPETITIVE BIDDING

Senator HARKIN. Mr. Clock, thank you very much.

Well, I guess my first question right out of the box is: You did not address the issue of competitive bidding.

Would your industry be in favor of competitive bidding similar to what the Veterans Administration? And have you looked at my pending legislation, S. 1193, and what we have in there?

Mr. CLOCK. I have not seen that, Senator. HIDA will forward information to you relative to answers to that question. However, I can say that relative to wound management supplies, that we would very much be opposed to competitive bidding.

There are several reasons for that, and this is just my thought process on how that works. Perhaps compared to the WIC Program, I do not know how many SKU's or line items you were talking about in that competitive bidding situation, but I know in our environment, we are talking probably about 500 to 700 different SKU's or line items.

Senator HARKIN. Forget about that. Forget about WIC. Look at the Veterans Administration. They buy the same stuff.

Mr. CLOCK. Yes.

Senator HARKIN. And they do competitive bidding.

Mr. CLOCK. They do, and I am not sure those numbers actually reflect the administration of the transportation, inventory control and the other expenses that the VA has that relates to the actual utilization of those supplies. Do you know, sir?

Senator HARKIN. I do not know the answer to that question.

Mr. CLOCK. OK. That might change your figures a little bit.

Senator HARKIN. Because of the administration of the program?

Mr. CLOCK. Yes; the administration of the inventory, the inventory management, the handling of the product, the breaking down

of the product at the distributor's site to smaller units of distribution. There is an expense associated with that.

Senator HARKIN. That is a good question. I will find out the answer to that. We will find out. That is a good point. We will found out about that, what that is.

However, it would be my intent, under the legislation that I have introduced, to put out for competitive bids on a regional or metropolitan area basis. I do not see HCFA supplying or warehousing or anything like that.

It would be just simply: Here is last year. Here is what we need. Put a bid out for tape. Put a bid out for this. Here is what we need for the area.

It may vary, and just put it out for bids.

Mr. CLOCK. Again——

Senator HARKIN. So it would be a little bit different than what the Veterans Administration does.

Mr. CLOCK. Sure. I understand. From the perspective of the people that we serve—and again, we are in rural Kansas, like you are in Iowa—I would suspect that the delivery mechanisms would not be the same there as it would be into a hospital or VA environment.

I am suspecting that there are differences between the method of delivery. I am, again, thinking of our perspective of long-term care and specifically nursing homes. There is a very high degree of cost associated with education of the people in the centers, as well as delivery of the product.

Senator HARKIN. I understand. Well, if you can get that information to me, I would appreciate it.

Mr. CLOCK. OK.

Senator HARKIN. Why it might not work in certain areas.

Mr. CLOCK. OK. Right. I do not have all the parameters. I think, however, that as a general rule, you will find that of the membership that we have in HIDA—and I think there are about 900 distributors—if you pared that down to 5, that is cutting out an awful lot of distributors who may in fact want to bid in this process. And yes, there would be some economies involved, Senator.

Senator HARKIN. Well, let them bid. They can bid.

Mr. CLOCK. Yes; I believe that. But there again, a lot of us are not necessarily large enough to be able to make a competitive bid of that magnitude. And we do not service perhaps as large an area as your region might project.

Senator HARKIN. Well, the reason for Medicare is to provide for elderly and disabled quality, affordable health care at the lowest possible cost to the taxpayers.

Mr. CLOCK. Yes; exactly.

Senator HARKIN. And that is what we are trying to do.

Mr. CLOCK. I will agree.

Senator HARKIN. And the purpose is not to keep certain businesses in business. I mean, if they cannot compete, then they cannot compete on a competitive bid basis.

I think most small ones out there could and should compete, just depending on their situation and where they are located.

I would also again ask for any information you can give me in these regards.

Last, I know that the Office of inspector general did base its findings on screens and authorities that were not put in place until yesterday.

But nonetheless, HCFA's blunder did lead to significant loss to the taxpayer. But again, in a lot of cases suppliers in your organization, I think, took advantage of the lack of Medicare's guidelines. I mean, you just cannot defend anyone billing for 240 yards of tape a day.

Mr. CLOCK. I agree.

Senator HARKIN. You cannot defend that.

Mr. CLOCK. I wholeheartedly agree with that.

Senator HARKIN. So some of these people—I mean, I do not know what kind of system you set up to police your own, but this kind of thing needs to be policed.

Mr. CLOCK. OK. I agree with that. I think that the record should state that 93 percent of the providers basically are providing their business in an appropriate manner.

At least that is the inference I would get from this report, which—I certainly would not throw the baby out with the bath water. Again, that is my personal assessment.

I did have one question, Senator. The package that you had there, the gauze pad, could you hold that up for me, please?

Senator HARKIN. This one right here?

Mr. CLOCK. Yes, sir; does that have an adhesive border on it?

Senator HARKIN. I will open it up and find out. I do not know. No; it is just a little piece of cotton—or something. I do not know what it is.

Mr. CLOCK. OK. Just so we are all talking the same tune.

Senator HARKIN. No; it does not have an adhesive border.

Mr. CLOCK. That particular piece of equipment that you are showing there, the sterile gauze pad—that is less than 16 square inches.

Senator HARKIN. Yes; I guess it is.

Mr. CLOCK. As applied, that is—well, a 2 by 2 inches is less than——

Senator HARKIN. This must be about 3 inches by 6 or something like that.

Mr. CLOCK. OK. It is less.

Senator HARKIN. Yes; so what?

Mr. CLOCK. OK.

Senator HARKIN. Well, it is 2 inches by 2 inches.

Mr. CLOCK. OK; 2 by 2 inches, yes, sir, that is correct.

Senator HARKIN. I guess you have to fold it over. Then it is 2 by 2 inches.

Mr. CLOCK. OK. According to the new DMERC guidelines, that particular dressing is coded K0216. It is described as gauze, nonimpregnate—in nonimpregnated, pad size 16 square inches or less, without adhesive border.

And just for the record, I would like for you to know that any supplier that bills that to any DMERC right now is being reimbursed at the rate of 7 cents. So I think your figure up here is—those may be a little bit high from the pharmacy side. That is my comment on it.

Senator HARKIN. My staff tells me that item probably did have an adhesive border. So this is not the same.

Mr. CLOCK. Oh, OK. All right.

Senator HARKIN. So it did have an adhesive border. Maybe we have a little bit of confusion here about which item we are talking about here.

Mr. CLOCK. All right. That is fine. It is easy to confuse, Senator.

Senator HARKIN. But this one here is 7 cents you say now.

Mr. CLOCK. Well, the reimbursement, yes, sir, is 7 cents. Right. That is what my staff told me this morning.

Senator HARKIN. I wonder what the VA is paying for it. I would just like to know what the VA is paying for. If they are paying 7 cents, I wonder if the VA is paying 2 or 3 cents for it.

Mr. CLOCK. Hard telling.

Senator HARKIN. Well, if the VA is paying 4 cents for this one—with the adhesive border, the VA was paying 4 cents.

Mr. CLOCK. With the adhesive border?

Senator HARKIN. I do not understand.

Mr. CLOCK. We probably need to get in touch with their supply sources, Senator. I think that would be a good idea for me.

Senator HARKIN. Well, I will find out. That is what I am told, that it is the same thing; 4 cents for VA, 17 cents Iowa, 86 cents HCFA. Obviously, that is not this one. I held up the wrong one.

Mr. CLOCK. OK. On the other item, the other K code, you are absolutely correct, sir.

Senator HARKIN. Well, I appreciate your being here and your testimony and the things we discussed. If you can give me some of that information, it would help us in our deliberations.

And also, your thoughts and your views on competitive bidding and any problems that might arise if we do go to strict—and look at the legislation we have and look at it, how we set it up in there.

And I would welcome any input that you have on that. There may be some problems that we had not foreseen.

Mr. CLOCK. All right, sir. I appreciate that. I am sure we will get back with you on that issue.

Senator HARKIN. Thank you, Mr. Clock.

Mr. CLOCK. Thank you.

PREPARED STATEMENT OF THE COUNCIL OF NURSING HOME SUPPLIERS

Senator HARKIN. We have an additional submitted statement from the Council of Nursing Home Suppliers which will be inserted into the record at this point.

[The statement follows:]

STATEMENT OF THE COUNCIL OF NURSING HOME SUPPLIERS

The Council of Nursing Home Suppliers (CNHS) is an organization comprised of health care providers and suppliers that provide services to Medicare Part B beneficiaries residing in long term care facilities. CNHS members furnish surgical dressings; prosthetic devices, such as ostomy supplies, urological supplies, and parenteral and enteral nutrition (PEN); orthotics, and splints and casts. The services which are provided to Medicare-eligible beneficiaries are those defined within the prosthetic device, orthotic and surgical dressing benefits (42 U.S.C. 1861(s)(5), (8) and (9)). A physician's authorization is required.

CNHS is pleased to present its comments to the Subcommittee on three draft reports of the HHS Office of Inspector General entitled: "Questionable Medicare Payments for Wound Care Supplies;" "Marketing of Wound Care Supplies;" and "Wound Care Supplies: Operation Restore Trust Data."

After reviewing the three draft reports, we are disturbed by the methodology used and the conclusions in the report. The reports are based on an approach to gathering data that was totally flawed: retrospectively using guidelines that went into effect only yesterday, October 1, 1995. In addition, the conclusions are not supported by the data, which demonstrates that steps already taken by the Health Care Financing Committee (HCFA) and the Durable Medical Equipment Regional Carriers (DMERC) have decreased costs to the Medicare program for wound care supplies. Further, shifting the surgical dressing benefit from the ancillary service category into the routine service category and including it with the routine costs of skilled nursing facilities, seriously jeopardizes patient care and misunderstands the behavior of nursing homes operating under cost limits.

CNHS, in collaborations with the National Coalition for Wound Care, worked with HCFA and the DMERCs in order to develop consensus recommendations for clinically appropriate utilization of wound care products. The wound care benefit, as stated in Section 2079

of the Medicare Carriers Manual, is medically sound and reflects the current clinical knowledge of wound care practice and technology. Our concern is that the benefit could easily be nullified by the OIG's conclusions.

The OIG methodology consisted of interviewing DMERC officials, both orally and by questionnaire, about wound care processing and practices and analyzing a one percent sample of wound care beneficiaries who received wound care supplies between June 1994 and February 1995. These claims were then compared to the proposed DMERC draft guidelines for surgical dressings to identify what they termed as "questionable" billing practices and marketing practices of wound care suppliers.

We do not understand how the OIG's approach can be considered valid. We fail to see how valid data can be collected and analyzed using guidelines that were not yet in effect. It is unacceptable and inappropriate to evaluate wound care practices using guidelines that suppliers of the products were unaware of at the time the service was provided. In addition, at the time of the sample, the draft guidelines had not yet been subject to public comment and had not been evaluated by the medical community. To our knowledge, no one other than the DMERC Medical Directors found them to be medically sound or appropriate. There was no assurance that the guidelines were proper and clinically correct. Thus, the conclusions reached cannot be considered reliable because it was not known at that time whether the guidelines were medically sound and reflected current medical practice. Before using the draft guidelines to evaluate claims, we believe it is imperative that the measuring tool, i.e., the draft guidelines, be shown to be reliable so that accurate and valid results will be achieved.

Moreover, the OIG failed to adequately consider the effects of consolidating claims processing into four DMERCs. This transfer and consolidation was intended as a way to more closely monitor Part B services for costs and fraud and abuse. The DMERCs have been in existence for a little more than a year. It would have

been more reasonable - and the results more accurate - to delay claims comparisons until after the DMERCs policies had been implemented.

Had the OIG carefully looked at the data collected, it would have seen that the DMERC transition has already resulted in decreased costs ("Wound Care Supplies: Operation Restore Trust Data," p.2, Table 1). Between 1993 and 1994, the number of beneficiaries receiving wound care supplies increased from 86,600 million to 127,300 million, a not unexpected result given the expansion in the wound care benefit. Yet, between 1993 and 1994, Medicare allowances decreased from $132 million to $98 million and the cost per beneficiary decreased from $1,526 to $769. Thus, the OIG's own data demonstrates that total wound care supply costs are on their way down.

The OIG's preconceived conclusion (and we have no doubt it was preconceived) - shifting the wound care benefit from the ancillary service category into the routine service category - demonstrates a lack of clinical knowledge of wounds and wound care supplies, and the behavior of nursing homes operating under routine cost limits.

First, surgical dressings are not "routine" services. According to 2203.1 of the Carrier's Manual, routine services are general nursing services, including administrating of oxygen and related medications, handfeeding, incontinency care, tray service, enemas, etc.; items furnished routinely and uniformly to all patients, such as patient gowns, paper tissues, water pitchers, basins, bed pans; items stocked at nursing stations or on the floor in gross supply; and items which are reusable, such as ice bags, canes, crutches, walkers.

Ancillary services, on the other hand, are those services described in 2203.2 of the Carriers Manual. They are direct identifiable services to individual patients and not generally furnished to most patients. They are not reusable; they represent a cost for each preparation; or they are complex medical equipment. Surgical supplies, by their very nature, are ancillary services.

We estimate that less than 10% of the Medicare beneficiaries residing in nursing homes qualify for the wound care benefit and receive surgical dressings.

Skilled nursing facilities are subject to routine cost limits for the payment of the services they provide to Medicare beneficiaries. Many facilities are near or at their cost limit. Adding the costs of the wound care benefit may very well push many nursing homes over their cost limits. Because of the additional costs, some nursing homes may not be able to provide the wound care service. Medicare beneficiaries with surgical wounds or decubitus ulcers would be denied this covered and medically necessary service <u>because</u> they reside in a skilled nursing facility.

Should the nursing home attempt to provide this benefit, the quality of patient care may suffer. Nursing homes will order surgical supplies based on their costs, not necessarily their appropriateness. Thus, wound care supplies received may be inappropriate for the particular type of wound, thus delaying healing of the wound and compromising the health of the patient.

In addition, nursing homes may begin refusing to accept eligible patients who are acutely ill or have complex medical problems. Because this type of patient often requires more advanced medical services - for example, a patient with multiple stage III decubitus ulcers - the nursing home may find it more cost effective to deselect the more acute patients for admission. Given the incentives of the hospital prospective payment system to discharge patients early, where will these beneficiaries go? Back to the hospital, thus increasing the cost? To home, where proper medical care cannot be provided, so that the patient must return to the hospital? It is in the best interests of the nursing home to keep its costs as low as possible. Surgical dressings and proper wound care practices may be sacrificed in order to keep the nursing home viable.

Furthermore, many wound care supply companies provide a "value-added" service along with the wound care supply. These

value-added services include educating nursing home staff about the different types of wounds and the correct application of the product. Long term care facilities, especially those located in rural areas, do not have the experienced personnel who understand the intricacies of some wound care products and current wound care clinical practices. There is also a high turnover in personnel in nursing homes, necessitating continued "re-education" of new employees. In addition, some nursing homes, especially nursing homes located in rural areas, do not have the capacity to store the different types of products or the ability to obtain the wound care product quickly when ordered by the physician.

Finally, the OIG identified several supplier companies responsible for what the OIG considers to be excessive billing practices. One of the reports states that these suppliers make up approximately seven percent (7%) of the supplier community. Based on the data used by the OIG, it should be noted that 93% of the supplier community are operating their businesses in a responsible manner.

We do not understand the failure of the OIG to suggest prosecuting those companies that may have billed in excess, or of placing these companies on postpayment reviews or repayment programs. In addition, the Secretary has the authority to exclude suppliers from participating in the Medicare and Medicaid programs if abusive practices are uncovered. We believe that the most effective method of eliminating fraud and abuse is to sanction those companies, or prosecute them and exclude them from federal health programs. Such sanctions will not only weed out fraudulent or abusive suppliers, but also serve as a deterrent.

In conclusion, the three draft reports by the OIG on wound care supplies and Operation Restore Trust do not accurately reflect current practice because they are based on a flawed methodology. Their validity must be questioned because they compare practices surveyed from June 1994 to February 1995 with guidelines that

became effective on October 1, 1995. The conclusion to include the costs associated with wound care supplies in the routine costs of skilled nursing facilities fails to recognize the nature of wounds and wound care supplies. To include surgical dressings in the skilled nursing facility routine costs could result in the elimination of the benefit for beneficiaries residing in nursing homes.

If we can provide the Subcommittee with additional information, please do not hesitate to contact Frank Case, legal counsel, or Sharon Hildebrandt, director of government relations.

CONCLUSION OF HEARING

Senator HARKIN. Thank you very much. I appreciate very much everyone being here. The subcommittee will stand in recess subject to the call of the Chair.

[Whereupon, at 11:31 a.m., Monday, October 2, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

○

ISBN 0-16-052254-4